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CONFIDENTIAL

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FINAL REPORT

DETERMINATION OF PERSONAL EXPOSURES TO ENVIRONMENTAL TOBACCO SMOKE IN BRITISH NON-SMOKERS

Report for:
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AUTHENTICATION

REPORT NO 12/64-1012

I, the undersigned, hereby declare that the work described was performed under my supervision, in accordance with the Hazleton Manual of Standard Operating Procedures, and that the report provides a true and accurate record of the results obtained.

K. Phillips

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Study Director
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Date: 15 June, 1993

I, the undersigned, hereby declare that I have reviewed this report in conjunction with the Study Director and that the interpretation and presentation of the data in the report are consistent with the results obtained.

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Date: 15 June 1993

The following scientific personnel were involved in the study under the overall supervision of the Study Director.

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The study described in this report was subject to audit/inspection by the independent HUK Quality Assurance Unit for the aspects and at the intervals specified below. The findings of each audit were reported to the Study Director and HUK management as prescribed by QA Standard Operating Procedures.

Phase of study audited	Date of audit	Date of report
Protocol review	15 October 1992	15 October 1992
Study Inspection	13 October 1992	15 October 1992
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Date: 16 June 1993

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KEY TO ABBREVIATIONS USED IN FIGURES AND TABLES

Sub	- Subject
No	- Number
PAS	- Particles from all Sources
UVPM	- ETS Particles as estimated by Ultra-violet Spectroscopy
FPM	- ETS Particles as estimated by Fluorescence Spectroscopy
SPM	- ETS Particles as estimated from Solanesol determination
3-eth	- 3-ethenylpyridine
Pre Cot	- Salivary Cotinine sampled prior to monitoring period
Post Cot	- Salivary Cotinine sampled at end of monitoring period
ETS	- Environmental Tobacco Smoke
ND	- Not Detected
NA	- Not Analysed
Sp'se	- Spouse
P'ner	- Spouse or Partner
N	- No
Y	- Yes
$\mu g/m^3$	- Micrograms per Cubic Meter
ng/mL	- Nanograms per Millilitre
M	- Male
F	- Female
Mod	- Moderate
V	- Very

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1. SUMMARY

During the Autumn of 1992, British volunteers were recruited to wear personal monitors for 24 hours in order to assess ETS exposure. All volunteers were recruited on the basis that they lived or worked in Leeds or Harrogate, that they were non-smokers and that they were taking part in an Air Quality survey. Out of 327 subjects, 72 were excluded for various reasons, including 53 suspected of smoking and 255 valid monitoring sessions were completed.

Measurements were made of exposure to particles form all sources, particles associated with ETS, and nicotine. Subjects supplied saliva samples for cotinine analysis at the start and end of the monitoring period and a questionnaire about smoke exposure and general lifestyle was completed.

Questionnaire data showed that approximately 80% of subjects assessed their ETS exposure as either 'none' or 'low'. Direct measurements of exposure by personal monitoring support this and also show that the mean overall levels for ETS particles was 12 $\mu g/m^3$, for nicotine 1.7 $\mu g/m^3$ and for the pre and post cotinine 1.4 ng/mL.

ETS particles were found to be only a relatively small percent (7%) of particles from all sources.

Subjective assessments indicate overall that the ranking of sources of exposure is LEISURE > WORK > HOME > TRAVEL. Over 40% of subjects assessed leisure as their principal source of exposure. Travel was perceived as only a minor contribution to total ETS exposure. In contrast, data derived from 24 hour measurements by personal monitoring indicate the ranking is HOME > LEISURE > WORK > TRAVEL. Both subjective and directly measured estimates indicate that travel was a minor source of exposure.

Results indicate that for the group as a whole, non-smokers with a spouse/partner who smokes are exposed to more ETS than non-smokers with a spouse/partner who is a non-smoker. However, there are marked variations among individual subjects. For

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example, 46% of non-smokers with a smoking spouse/partner assessed their ETS exposure as 'none' or 'low'. Direct measurements supported these assessments. Also, approximately 30% of the subjects with a smoking spouse/partner assessed work or leisure as their principal source of exposure.

Overall the Direct Measurements of SPM, nicotine and salivary cotinine levels were consistent with subjective assessments of exposure obtained by questionnaire. However, there was considerable variation in the way individual subjects perceived similar ETS levels. This demonstrates that an individual's exposure to ETS cannot be reliably assessed by the use of a simple questionnaire but there should be supplementary information obtained from direct measurements.

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2. INTRODUCTION

Two main approaches have been used in the past to assess whether there is any risk associated with exposure to ETS. One is based on epidemiology and the other on the quantities of smoke constituents to which non-smokers are exposed.

A criticism of published epidemiological studies of ETS exposure is that they failed to include direct measurements of exposure levels. Spousal smoking has frequently been used as an index of ETS exposure in these studies but the validity of this approach is open to question. Therefore, it is important to determine whether reported spousal smoking correlates well with directly measured exposure. It is also important to assess how well directly measured ETS exposure can be predicted by questionnaire, or by measurements of salivary cotinine, because these methods are also used as an alternative to direct measurements of exposure.

Most of the information about the exposure of non-smokers to ETS is based on measurements of ETS levels in locations such as homes, offices, and restaurants together with assumptions about the time people are thought to spend in these locations. There have been several such studies conducted, particularly in the USA, but none has provided sufficient information to characterise properly the range of ETS exposure experienced by non-smokers.

There have, until recently, been few attempts to measure directly the exposure of people as they go about their normal lives, moving from location to location, even though this approach should provide more realistic results than those calculated from ETS levels in locations. Although the use of 'personal monitoring' has been common practice in the industrial hygiene field for several years, it is only recently that the analytical methodology has been refined sufficiently to allow ETS measurements to be carried out by this approach. A few ETS exposure studies involving personal monitoring have now been completed or are underway. Nevertheless, further information is required with which to address some of the important issues relating to ETS.

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Although levels of both nicotine and ETS particles have been determined in several studies of locations, personal monitoring studies have tended to measure nicotine but not particles. In view of the limitations of nicotine as a marker for ETS and the importance often attached to particles, there clearly is a need for personal monitoring studies in which nicotine and ETS particles are measured simultaneously. This is possible now that the UVPM (ie ETS particulate matter measured by ultra-violet light), FPM (ie ETS particulate matter measured by fluorescence) and solanesol methods are available for estimating the ETS contribution to total particles.

There is an increasing trend for smoking bans to be introduced in the workplace and in various public leisure and travel situations. There is also increasing debate about smoking at home, especially in the presence of children. Therefore it would be helpful to obtain further information on the extent of exposure at home, work, leisure and travel in order to assess how each contributes to overall ETS exposure. This type of objective data would allow decisions about ETS exposure to be taken on a more informed basis.

The specific objectives of this project were as follows:

1. To determine the range, mean and median levels of 24-hour exposure to nicotine and to ETS particles for non-smoking British volunteers.

2. To assess the contributions to total ETS exposure from the home, the workplace, leisure and travel.

3. To assess whether non-smokers who are married to smokers have significantly higher exposures to ETS than non-smokers married to non-smokers.

4. To compare questionnaires, direct measurements and salivary cotinine levels as methods of assessing exposure to ETS.

To meet these objectives, 327 non-smokers were randomly selected for the study. Each subject's exposure to ETS was determined over a 24 hour period by a personal

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monitoring method. Measurements were made of nicotine and particles from all sources. The contribution of ETS to the total particles collected was assessed by UV, fluorescence and solanesol measurements.

Although not a part of the agreed objectives, 3-ethenylpyridine was also measured as it was collected and analysed simultaneously with nicotine.

Subjects completed a time-activity diary during the monitoring period which included a record of whether tobacco smoke was present. A post-sampling questionnaire was completed on perceived exposure levels, times spent in various locations, smoking by spouse or partner etc. The subjects were not aware that the study was related to ETS as they had been told that it was an air quality study.

Cotinine levels were measured in saliva samples taken at the beginning and end of the monitoring period.

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3. STUDY DESIGN

3.1 Pilot study

Prior to the start of the main study, a pilot study was conducted using ten subjects. The purpose of the trial was to evaluate and assess all aspects of the study design. This included evaluation of the delivery and collection of monitors, completion of diaries and questionnaires, and analysis of samples. This pilot study was successful and resulted in only minor modifications being incorporated into the main study.

3.2 Main study

3.2.1 Subject selection

280 non-smokers were randomly selected from an existing data base of 15,000 volunteers held at Besselaar Clinic, Leeds, England (See Appendix 2). The subjects were either working or resident in the Harrogate or Leeds postal districts for at least three months prior to and during the study period. Their ages ranged between 21 and 61 years and selection was reasonably representative in terms of age and sex distribution (see Appendix 6.8). As subjects dropped out, did not keep their appointments, pumps failed, reported non-smokers were identified as smokers, further subjects were recruited bringing the total number of subjects included to 327. There were approximately 70 different occupations including housewives, policemen, musicians, solicitors, mechanics, civil servants, dentists, cooks etc. (See Appendix 6.7).

3.2.2 Delivery and collection of monitors

All locations were selected by Besselaar Clinic's staff in advance (see Appendix 2). Regular contact with the clinic and Hazleton UK was maintained by car phone during delivery and collection.

Deliveries were in the mornings in Leeds and the afternoons in Harrogate. Generally collection was after 24 hours but in all cases was between 23 and 25 hours following delivery.

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3.2.3 Start of the monitoring period

On delivery, the use of the pump and wearing of the monitor was explained. A diary was provided for completion during the monitoring period. The pump was switched on by the investigator and a saliva sample obtained (pre sample) by the subject chewing on a dental swab for a measured 1.5 minutes (Appendix 3).

3.2.4 End of the monitoring period

On collection, the pump was switched off by the investigator. A post saliva sample was taken in an identical way to the pre-sample. Diaries were checked and collected and the questionnaires completed by the investigator who asked the questions and recorded the answers.

3.2.5 Collection and analysis of airborne nicotine, 3-ethenylpyridine and particulates

The collection of these analytes was achieved by the subjects wearing the compact monitor and pumping system (See Appendix 3, Figure 2) for the duration of the monitoring period. The first filter of the two in series collected the particles from all sources (PAS) and the second, which was acid-treated, trapped the nicotine vapour and 3-ethenylpyridine.

At the end of the monitoring period the filter holders were returned to Hazleton UK, Harrogate, England for analysis. The filters were weighed to determine PAS and extracted with methanol. The extracts were analysed for nicotine, 3-ethenylpyridine, UVPM (particles measured by UV light), FPM (particles measured by fluorescence) and solanesol (SPM).

3.3 Methods of analysis (in brief)

Summaries of the methods of analysis are presented here. Full details can be found in Appendix 4 together with appropriate calibration data and typical chromatograms.

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3.3.1 UVPM, FPM and SPM

The particles from all sources collected on the Millipore Teflon filters were extracted with methanol. UV and fluorescence measurements were made on the extract using an HPLC method (without the use of a column) and compared to calibrations made using surrogate standards for ETS particulates (Scopoletin for FPM and Tetrahydroxybenzophenone (THBP) for UVPM). These surrogate standards were themselves calibrated by the sponsor against ETS particles generated in a Model Room.

The solanesol content of the extract was determined using an HPLC method with UV detection. Solanesol based ETS particles (SPM) were determined using a factor calculated from the solanesol content of ETS particles generated in a Model Room. This factor was supplied by the sponsor.

3.3.2 Nicotine and 3-ethenylpyridine

Any nicotine and 3-ethenylpyridine collected on the front filter was extracted as above. An aliquot of this extract was basified with sodium hydroxide solution and the nicotine and 3-ethenylpyridine extracted using di-isopropylether containing triethylamine and an internal standard.

Nicotine and 3-ethenylpyridine collected on the second filter was extracted following basification as above.

The nicotine and 3-ethenylpyridine were determined using a GC method with nitrogen selective detection.

3.3.3 Cotinine

Saliva samples were centrifuged in their salivettes. Internal standard (N-ethylnorcotinine) was added to 0.5 mL of the saliva which was then extracted using dichloromethane under basic conditions. The cotinine was determined by GC using a mass selective detector.

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4. RESULTS AND DISCUSSION

4.1 Excluded subjects

All results for some subjects were excluded from the study for the following reasons:

REASON	NUMBER EXCLUDED
Subjects did not keep their appointment	5
The pump did not run for the full 24 hours	6
One of the Hazleton analysts was a smoker*	14
Smoke was deliberately blown into the monitor	6
Subjects admitted smoking during the monitoring period	7
Subjects had salivary cotinine levels above threshold	34

* On one occasion an analyst who claimed to smoke occasionally was involved with the testing of a batch of personal monitors. This was in breach of the protocol and the results from 14 subjects were invalidated.

Thus from 327 subjects selected, 72 were excluded and 255 sets of usable results were obtained.

Seven subjects were rejected for smoking during the monitoring period (questionnaire) and 34 subjects were rejected with cotinine levels $\geq$ 25 ng/mL. For the purposes of this study they were assumed to be smokers but some could conceivably be users of other forms of nicotine administration (eg gum, patches). The questionnaire did not address the use of other forms of nicotine administration. However, none of the subjects volunteered any such information, although questioned in detail about their smoking habits.

The 34 subjects who were excluded as a result of high cotinine levels were contacted by phone and letter after completion of the study. Responses were received from 17 of these 34 subjects. Fifteen of these confirmed that they had not used any form of nicotine administration system and these subjects must therefore be regarded as smokers.

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In a review of salivary cotinine levels, Etzel (1990) reported that non-smokers usually have levels below 5 ng/mL, but heavy exposure can result in levels around 10 ng/mL. The 25 ng/mL criterion used in this study was chosen to avoid the possibility that heavily exposed non-smokers might be incorrectly rejected.

There is some debate as to what salivary cotinine cut-off level should be used to detect smokers or nicotine users. From the 327 subjects tested in this study, the number that would be rejected at different cut-off levels of salivary cotinine is as follows:

Cut-off level	Number rejected
10 ng/mL (Etzel, 1990)	47
15 ng/mL (McNeill, 1987)	41
25 ng/mL	41
30 ng/mL (Lee, 1987)	37
50 ng/mL	34
100 ng/mL (EPA criterion for regular smoker see Section 4.2)	23

These results show that the salivary cotinine cut-off point used to distinguish between smokers and non-smokers on this study is not very critical, especially in the range 15 to 30 ng/mL.

Some of the subjects were found to have very high cotinine levels and those with levels ≥ 100 ng/mL are listed below to indicate the number of subjects involved and the range of levels in which they were distributed. Sixteen subjects had pre or post cotinine levels > 300 ng/mL, the highest being > 700 ng/mL.

Excluded subjects

Number of subjects	Cotinine range (ng/mL)
2	100 - 150
3	150 - 200
1	200 - 300
7	300 - 400
7	400 - 500
2	500 - 800

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4.2 Misclassification

Misclassification occurs in ETS studies when smokers report themselves as non-smokers, or vice-versa. This has important consequences when attempts are made to assess whether there is any risk associated with ETS exposure (Lee 1988).

It was not an objective of this study to assess misclassification and it was not anticipated that it would occur to a substantial level especially as the subjects were members of a documented group held on a data base used for medical trials.

All subjects were recruited on the basis that they were non-smokers. Also, a recruitment questionnaire was completed for each subject confirming this non-smoker status.

In view of these recruitment criteria, it was surprising to find that 41 subjects had to be excluded for smoking, or possibly other nicotine usage. Furthermore, 12 other subjects admitted smoking following recruitment as non-smokers. These 12 subjects were not excluded from the study because they did not smoke near to the time of their monitoring session (Questionnaire) and they were not identified as smokers by their salivary cotinine measurements.

The median salivary cotinine level for self reported smokers (or nicotine users) in the UK was reported by LEE (1987) to be 319 ng/mL for men and 311 ng/mL for women. The EPA has defined regular smokers as those with more than 30% of the average cotinine level found for smokers.

Therefore some subjects, especially those with cotinine above 100 ng/mL, were likely to be regular smokers and had, nevertheless, incorrectly described themselves as non-smokers. Others may have been occasional smokers and yet genuinely regard themselves as non-smokers. This indicates that careful questioning is required to determine if a person, or a person's spouse, is a smoker.

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Because 12 subjects admitted to recent occasional smoking (Questionnaire) and yet were not identified as smokers by salivary cotinine measurements, it seems that such body fluid measurements could well underestimate misclassification rates in other studies.

It is possible that other subjects had smoked occasionally since recruitment, did not admit to doing so and were not detected by salivary cotinine level. A combination of a well-designed questionnaire and salivary or urinary cotinine measurements is clearly required to detect most cases of misclassification but even then some smokers may not be detected.

In summary:
Seven subjects admitted smoking during the monitoring period.
Twelve subjects admitted smoking since recruitment but not at the time of the monitoring period.
These 19 subjects were clearly misclassified as non-smokers.

Thirty-four subjects were suspected of smoking based on their salivary cotinine levels, 15 of these 34 subjects contacted after the study confirmed that they had not used any form of nicotine administration system such as gum or a patch.

These 15 subjects are almost certainly smokers. Two subjects contacted after the study reported that they had used a nicotine administration system (patches in both cases). The remaining 17 out of the 34 did not respond.

The level of misclassification of smokers as non-smokers found in this study is at least 10% (19 admitted smoking and 15 identified as smokers out of 327 subjects) but is probably much closer to 16% (53 out of 327 subjects). This is consistent with levels of misclassification found in other studies.

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4.3 Relevance of 24 hour sampling

In order to assess how representative the 24-hour sampling period was, subjects were asked to make a comparison of their ETS exposure during the sampling period with their average exposure over the last six months. The results were as follows:

Subjective assessment	Number	% of total
Much less than normal	25	9.8
Less than normal	91	35.7
Fairly typical of average exposure	131	51.4
More than normal	7	2.7
Much more than normal	1	0.4

Over 50% of subjects assessed their exposure in the monitoring period was typical of their average exposure. However, on balance, the subjects assessed their exposure to be somewhat less than normal.

For all subjects who claimed they were exposed to ETS during the monitoring period (156) subjective assessments were made of the relative contributions of home, work, leisure and travel to total ETS exposure. The mean values for these results in the monitoring period and for the previous six months are compared below.

	% Contribution to overall ETS exposure	
	Monitoring period	Last six months
Home	27.8	19.8
Work	31.5	29.4
Leisure	35.1	46.3
Travel	5.7	4.7

[It could be argued that the comparison of results for home and leisure indicate that wearing the monitor caused the subjects to spend more time, relative to the last six months, at home instead of at leisure. On the other hand, it is probable that subjects would spend more time at home in October to December (study period) than they would throughout the previous six summer months.]

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Objective evidence that the monitoring period was not abnormal relative to the previous day is that the mean results for the pre-monitoring salivary cotinine levels are in close agreement with the post-monitoring levels.

Taken together the subjective and objective results indicate that the monitoring period was not abnormal compared with recent exposure. This suggests that wearing the monitor did not seriously interfere with normal lifestyle.

4.4 Weather conditions during the study

It was decided not to conduct the study during the summer months when ETS exposure was likely to be at a minimum. Similarly, it was decided not to conduct the study during peak winter conditions when the exposure to ETS would probably be at its highest and the practical difficulties of conducting the study at their greatest. Therefore October to early December was chosen as a compromise time period.

Accurate information on the prevailing weather conditions between 4 October 1992 and 12 December 1992 was supplied by The Meterological Office, Leeds Weather Centre, Leeds, England. Measurements were observed daily for the Harrogate and Leeds districts with any significant differences being noted. The official data are in Appendix 6.6.

A summary based on weekly minimum, maximum and mean values (where applicable) of temperature, relative humidity, rainfall hours of sunshine and wind speed is presented in Figure 1.

It can be seen that there was a wide variation in weather conditions throughout the study. The minimum temperature recorded was -3.2°C and the maximum 16.9°C, both in early November. The minimum %RH was 55.0 and the maximum 96.0. The maximum daily rainfall was 10.4 mm. The maximum recorded sunshine was 7.5 hours during week 2 of the 10 week study. Wind speed varied from a low of 4 knots to a high of 26 knots. The highest gust recorded was 61 knots during

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week 4. Hail was observed on 10, 19 and 26 November 1992. Sleet was also observed on 25, 27 October and 12 November 1992.

In Figure 2 the mean weekly SPM and PAS values for the subjects monitored are listed together with the mean values of temperature, %RH and Hours of sunshine for the same periods. It can be seen that there is no obvious relationship between mean weather conditions and measured ETS exposure.

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FIGURE 1

WEATHER CONDITIONS (MEAN WEEKLY VALUES)

Date	Week number	Subject number	Temperature (°C)			Rainfall (mm)		% RH			Hours sunshine			Wind speed (kt)	
			Min	Max	Mean	Min	Max	Min	Max	Mean	Min	Max	Mean	Min	Max
6-12 Oct	1	1-37	7.3	14.2	9.9	0.0	5.0	61.0	76.0	67.6	0.0	5.0	1.5	6	11
13-19 Oct	2	38-68	-0.9	11.9	7.0	0.0	1.9	55.0	74.0	64.7	0.0	7.5	4.7	4	17
20-26 Oct	3	69-106	0.3	10.5	5.7	0.0	9.7	61.0	94.0	77.0	0.0	6.3	2.6	5	13
27-2 Nov	4	107-139	-0.2	12.1	6.9	0.0	4.5	60.0	88.0	71.7	0.0	7.0	4.4	7	26
3-9 Nov	5	140-179	-0.6	16.9	10.0	0.0	8.3	65.0	89.0	66.6	0.0	5.0	1.7	4	14
10-16 Nov	6	178-219	-3.2	8.8	4.5	0.0	5.9	62.0	91.0	77.9	0.0	7.3	2.7	6	18
17-23 Nov	7	220-251	1.3	15.0	7.8	0.0	10.4	54.0	96.0	76.4	0.0	6.7	2.8	4	20
24-30 Nov	8	252-289	-0.2	13.0	7.3	0.0	4.6	72.0	94.0	79.1	0.0	5.0	2.3	5	15
1-7 Dec	9	290-305	1.6	12.8	5.7	0.0	7.6	77.0	89.0	82.7	0.0	2.5	1.3	6	14
8-12 Dec	10	306-327	1.6	9.9	5.9	0.0	7.1	75.0	94.0	84.8	0.0	2.4	0.8	5	9

% RH = % Relative Humidity Wind speed kt = knots

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FIGURE 2

MEAN WEEKLY VALUES OF SPM, PAS, TEMPERATURE, % RH AND HOURS OF SUNSHINE

Week number	SPM ($\mu g/m^3$)	PAS ($\mu g/m^3$)	Temperature (°C)	% RH	Hours of Sunshine	Max wind speed (Kt)
	Mean	Mean	Mean	Mean	Mean	
1	10	177	9.9	67.6	1.5	11
2	9	157	7.0	64.7	4.7	17
3	13	220	5.7	77.0	2.6	13
4	18	187	6.9	71.7	4.4	26
5	6	161	10.0	66.6	1.7	14
6	14	196	4.5	77.9	2.7	18
7	4	141	7.8	76.4	2.8	20
8	21	180	7.3	79.1	2.3	15
9	8	159	5.7	82.7	1.3	14
10	28	214	5.9	84.8	0.8	9

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4.5 The analytical methods: General observations

Full details of the methods used are provided in Appendix 4.

4.5.1 Particles from all sources

It would have been preferable on this study to measure Respirable Suspended Particles (RSP) which are particles below a certain diameter (5 to 10 μ depending on definition). However, it would not have been possible to achieve the necessary size discrimination at the low sampling flow rate used in this study. At higher flow rates, an impaction device or a cyclone could be used to achieve the required size discrimination but the battery-operated sampling pump would then not have operated for 24 hours.

If particles are collected with no size selection at all then the collected material is referred to as Total Suspended Particles (TSP). Since the larger particles in TSP cannot be inhaled, less importance is attached to this measure.

The particles collected with the personal monitor used in this study are neither RSP nor TSP. Calculations (Dr I Colbeck, Essex University) based on the sampling flow rate and the entrance plate dimensions suggest that particles of respirable size ($<10\ \mu$ diameter), including ETS, would be collected very efficiently by the personal monitor and this has been confirmed experimentally by the sponsor. These calculations also indicate that the collection efficiency should fall to zero for particles of around 50 μ diameter or more.

To avoid any confusion with RSP or TSP, the term PAS is used in this report to refer to the Particles from All Sources as collected by the personal monitor.

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It is to be expected that the measurement of PAS will tend to give results which are a little higher than RSP and lower than TSP.

4.5.2 ETS Particles

ETS particle values reported in this Results and Discussion section are based on estimation by the solanesol method and are referred to as SPM (See Appendix 4). This method proved to be a more selective measure of ETS contribution than UVPM or FPM. Results for UVPM and FPM are given in Appendix 6.1.

As might be expected, UVPM measurements can considerably overestimate the ETS particle contribution to PAS because many particles not associated with ETS also absorb UV light. FPM measurements are less prone to interference than UVPM but there is still some fluorescence from particles that are not associated with ETS. Solanesol measurements are almost totally free from interference.

Clearly, the situation where the greatest over estimation of ETS by UVPM and FPM measurements is to be expected when a PAS level is high but the ETS contribution is very low.

The selectivity of the three methods is reflected in the individual, the mean and the median results obtained in the study (see Figure 4).

Ogden et al (1990) have compared the relative merits of the UVPM, FPM and solanesol-based methods for estimating ETS particle contributions to RSP. They also concluded that the UVPM method can considerably overestimate ETS particles, and that the FPM method is less prone to interference but is not as selective as solanesol-based methods.

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4.5.3 Salivary cotinine

Salivary cotinine measurements were made by a GCMS method. The detection limit was 0.5 ng/mL, which is higher than the best detection limit of 0.1 ng/mL reported for GC with nitrogen specific detection (NPD). However, experiments with GC-NPD showed that it was not possible to be certain of cotinine peak identification at low levels in saliva samples. This is due to the variable composition of the saliva matrix and the presence of nitrogen containing compounds with similar retention times to cotinine.

4.5.4 Detection limits

Detection limits for the analytical methods used were found to be as follows:

PAS	20 $\mu g/m^3$
UVPM	8 $\mu g/m^3$
FPM	4 $\mu g/m^3$
SPM	4 $\mu g/m^3$
Nicotine	0.1 $\mu g/m^3$
3-Ethenylpyridine	0.1 $\mu g/m^3$
Salivary cotinine	0.5 ng/mL

Reference to the tables of analytical results in Appendix 6.1 shows that in many cases levels of components are below the limit of detection for the method used. This raises the question of how to deal with these results in the calculation of means, medians etc in the data analyses. If a value of zero is applied when results are below the limit of detection then this would underestimate the true level of exposure for some subjects. Conversely, if the value of the detection limit itself was applied in such cases then the exposure of some subjects would be overestimated. As a reasonable compromise, a value which is one half of the detection limit has been used for the data analyses carried out in this report. The same compromise has been used in other studies of this type.

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4.5.5 Expression of mean results

When reporting results, both the mean and the median values of data sets are quoted together with the range of the values. In this type of study where the results are far from being normally distributed the median is a more appropriate measure than the mean because one or two exceptionally high values can have a disproportionately large effect on the mean when most of the other values are relatively low. Both the mean and the median will be referred to as appropriate, but generally most importance should be attached to median results.

4.6 Consistency of results with those from other studies

4.6.1 PAS

Results for PAS are reasonably consistent with results for RSP in other studies. However, the comparisons have to be made with the results from measurements in locations (see below) because there are insufficient data from personal monitoring studies.

Ogden (1990) has reported on the use of solanesol measurements for estimating the ETS contribution to RSP levels. However, only a limited number of results were reported which did not involve personal monitoring and cannot usefully be compared with the data from this study.

There have, however, been several recent studies in which UVPM has been measured and these have been summarised by Guerin et al (1992) as follows:

	Mean particle levels $\mu g/m^3$	
	UVPM	RSP
42 restaurants	26*	62*
10 trains, smoking compartments	60	216
10 trains, non-smoking compartments	33	186
5 betting shops	164	333
125 offices	27*	126*
82 restaurants	36*	126*

* geometric mean

Corresponding results for this study are consistent with the above results:

This study	31	179 (PAS)

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4.6.2 Nicotine

Nicotine levels found in this study are in good agreement with other recent studies. The most similar study to the current one is that reported by Proctor et al (1991) who measured the nicotine exposure of 52 women in Birmingham, England by a personal monitoring technique:

	Nicotine $\mu g/m^3$			
	Maximum	Minimum	Mean	Median
This study	26	0.05	1.7	0.5
Proctor et al	45	0	2.3	0

The results from these two studies for nicotine are in close agreement.

4.6.3 Cotinine

Salivary cotinine levels found in this study are also in close agreement with those reported by Proctor et al in the same publication:

		Salivary cotinine ng/mL			
		Maximum	Minimum	Mean	Median
This study	Pre-sample	14	0.25	1.4	0.7
	Post-sample	12	0.25	1.4	0.6
Proctor et al	Pre-sample	15	0.3	1.8	1.2
	Post-sample	9	0	1.5	1.1

The exposure levels measured in this study are in good agreement with results from other studies. This would indicate that the personal monitoring technique and analytical methods used in this study are valid.

4.7 Cigarette equivalents

Some authors have used the concept of 'cigarette equivalents' in an attempt to put ETS exposure levels into perspective. This approach has the advantage of providing the layman with a comprehensible measure of the quantity of ETS inhaled as a result of ETS exposure. However, the inhalation of ETS is different

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in several important ways from the inhalation of mainstream cigarette smoke during active smoking. It is therefore incorrect to equate ETS values with numbers of cigarettes smoked.

If a comparison with active smoking is to be made, the following should be taken into account:

a) The composition of ETS is quantitatively quite different from that of mainstream smoke.

b) The way compounds in ETS are taken up by the body may be different from the way that mainstream smoke components are taken up during active smoking.

c) A given quantity of a compound taken up by the body during a few seconds (active smoking) would be expected to have quite different effects from the same quantity taken up during many hours of ETS exposure.

Taking into account the above comments, the quantities of smoke components inhaled during exposure to ETS have been calculated on the basis of the exposure levels found in this study. These are compared below to the quantities of components inhaled by active smoking. No equivalence of these two forms of exposure is implied.

Two assumptions are made:

A. That adults breathe 1 m^3 of air per hour, ie 24 m^3 of air is inhaled during 24 hours.

B. That a 'typical' UK smoker smokes 15 cigarettes per day, each with a 10 mg nicotine-free dry particulate matter yield and a 1 mg nicotine yield.

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Using these assumptions and the values obtained during this study the following statements can be made:

ETS Particles

- A person smoking 15 cigarettes a day (10 mg particulate matter yield per cigarette) would inhale approximately 150,000 μg of particulate matter during 24 hours.

- A person continually exposed to the median ETS particles level of 2 $\mu g/m^3$ found in this study would inhale approximately 48 μg of these particles during 24 hours. Therefore, it would take this person more than eight years to inhale the quantity of smoke particles that a 'typical' smoker would inhale in one day.

- A person continually exposed to the mean ETS particles level of 12 $\mu g/m^3$ found in this study would inhale approximately 288 μg of these particles during 24 hours. Therefore, it would take this person 521 days to inhale the quantity of smoke particles that a 'typical' smoker would inhale in one day.

- A person continually exposed to the maximum ETS particles level of 159 $\mu g/m^3$ found in this study would inhale approximately 3816 μg of these particles during 24 hours. Therefore, it would take this person 39 days to inhale the quantity of smoke particles that a 'typical' smoker would inhale in one day.

Nicotine

- A person smoking 15 cigarettes a day (1 mg nicotine yield per cigarette) would inhale approximately 15,000 μg of nicotine during 24 hours.

- A person continually exposed to the median nicotine level of 0.5 $\mu g/m^3$ found in this study would inhale approximately 12 μg of nicotine during 24 hours. Therefore, it would take this person more than three years to inhale the quantity of nicotine that a 'typical' smoker would inhale in one day.

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- A person continually exposed to the mean nicotine level of 1.7 $\mu g/m^3$ found in this study would inhale approximately 41 μg of nicotine during 24 hours. Therefore, it would take this person 367 days to inhale the quantity of nicotine that a 'typical' smoker would inhale in one day.

- A person continually exposed to the maximum nicotine level of 26 $\mu g/m^3$ found in this study would inhale approximately 624 μg of nicotine during 24 hours. Therefore, it would take this person 24 days to inhale the quantity of nicotine that a 'typical' smoker would inhale in one day.

The following table summarises these calculations:

	ETS (as SPM)			Nicotine		
	Mean	Median	Maximum	Mean	Median	Maximum
Measured value ($\mu g/m^3$) this study	12	2	159	1.7	0.5	26
Total in 24 hours (μg)	288	48	3816	41	12	624
Time to inhale an amount corresponding to 1 day's typical active smoking	521	> 8 years	39 days	367 days	> 3 years	24 days
Typical smoker 15 cigarettes/day		150,000 μg/day			15,000 μg/day	

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4.8 Objective 1

To determine the range, mean and median levels of 24 hour exposure to nicotine and ETS particles for non-smoking British volunteers.

To meet this objective, ETS exposure was assessed by the subject answering a questionnaire, by direct measurement using personal monitoring and by measurement of salivary cotinine.

4.8.1 Subjective assessment by questionnaire

Figure 3 shows the subjective assessments of the 24 hour exposure made by all subjects. Approximately 80% of the subjects considered that during the monitoring period their exposure to ETS was either 'none' or 'low'. Only one subject reported exposure as 'very high'.

4.8.2 Direct exposure measurements

From the individual analytical results (See Appendix 6.1) the range, mean and median levels for each analyte were derived for all subjects. These summary data are given in Figure 4.

Figure 5 demonstrates that ETS particles make only a small contribution to PAS. This confirms that there are other significant sources of particles in the atmosphere as well as those from PAS. For this study the mean SPM level as a percentage of PAS for all subjects is 7.1%.

Figure 6 shows how SPM and nicotine results are distributed by subject.

For SPM, more than 70% of the subjects had exposure levels less than 10 $\mu g/m^3$. The mean is 12 $\mu g/m^3$, and the median 2 $\mu g/m^3$.

More than 60% of the subjects were exposed to less than 1 $\mu g/m^3$ nicotine. More than 85% of the subjects were exposed to less than 5 $\mu g/m^3$ nicotine. The mean for nicotine is 1.7 $\mu g/m^3$, and the median 0.5 $\mu g/m^3$.

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Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

The only subject assessing his ETS exposure as 'very high' had directly measured SPM and nicotine values well above average for the subjects as a whole, but no higher than for many other subjects. This subject's pre cotinine level was 0.6 ng/mL, about the mean for all subjects, but the post cotinine level was 5.7 ng/mL, significantly higher than average, but by no means the highest on the study.

4.8.3 Cotinine level measurements

Figure 7 shows how the data for pre and post cotinine levels are distributed by subject. The graphs show near identical patterns, with both the pre and post mean values at 1.4 ng/mL. The median levels for pre and post cotinine were 0.7 ng/mL and 0.6 ng/mL respectively.

Key analytical data by age and sex are shown in Appendix 6.5. From this table, male subjects had higher mean and median results than women for nicotine, SPM and pre and post cotinine levels.

If age groups are compared the results indicate that the highest median levels of ETS exposure for males and females are in the 21 to 29 age group.

The subjective assessments and the direct measurements indicate that for a large majority of subjects their ETS exposure was either 'none' or at a 'low' level.

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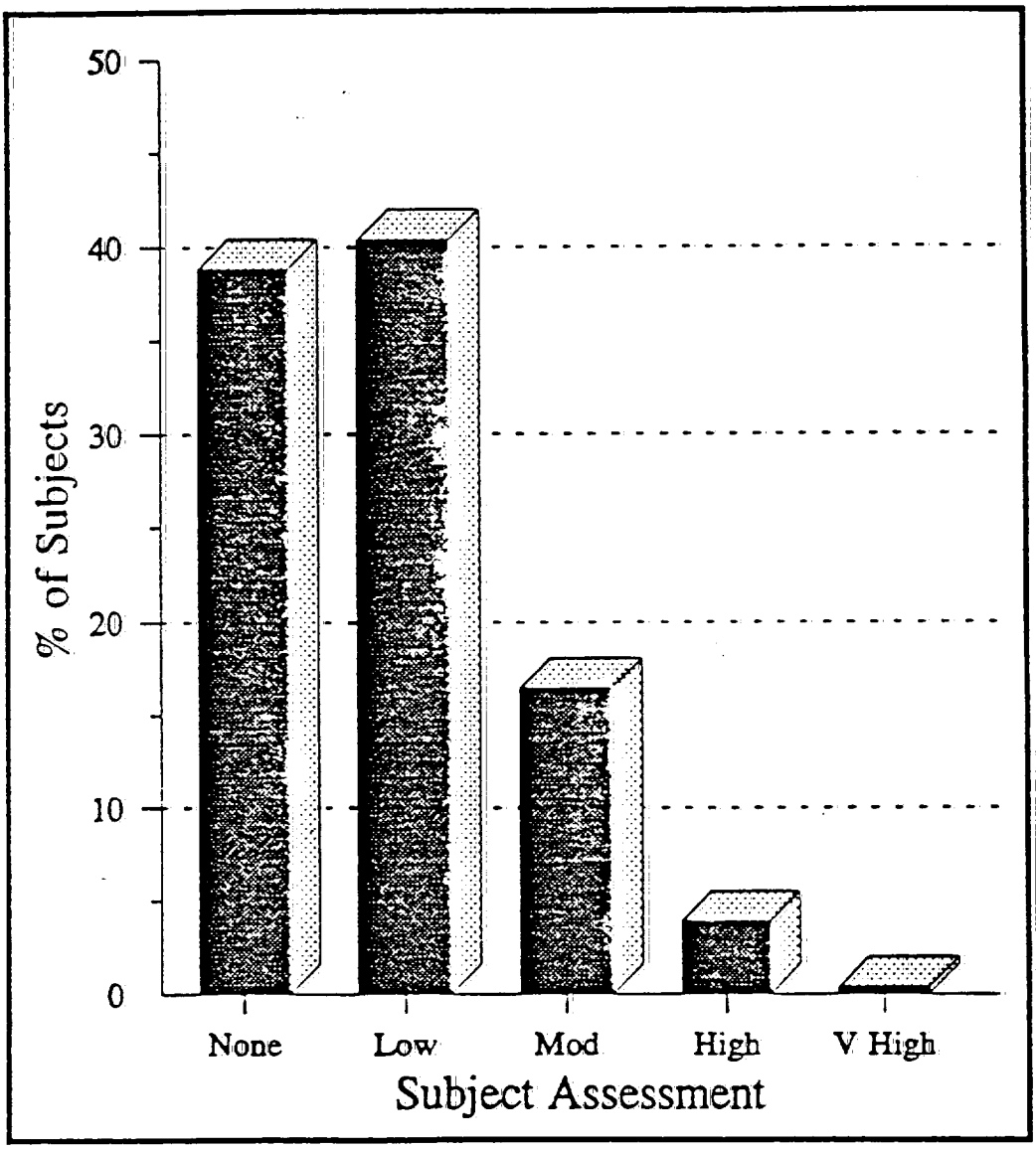
FIGURE 3

SUBJECTIVE ASSESSMENT OF AVERAGE EXPOSURE TO ETS DURING MONITORING PERIOD



Overall Number of Subjects = 255

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Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 4

SUMMARY STATISTICS FOR ALL ANALYTES AND ALL SUBJECTS

		Minimum	Maximum	Mean	Median	No Results
PAS	($\mu g/m^3$)	20	1219	179	142	255
UVPM	($\mu g/m^3$)	4	299	31	21	255
FPM	($\mu g/m^3$)	2	146	16	10	255
SPM	($\mu g/m^3$)	2	159	12	2	255
Nic	($\mu g/m^3$)	0.05	26	1.7	0.50	249
3-eth	($\mu g/m^3$)	0.05	4.2	0.38	0.05	249
Pre Cot	(ng/mL)	0.25	14	1.4	0.7	254
Post Cot	(ng/mL)	0.25	12	1.4	0.6	248

FIGURE 5

SPM AS PERCENTAGE OF PAS

Minimum	0.2	
Maximum	60.0	
Mean	7.1	(255 subjects)
Median	2.5	

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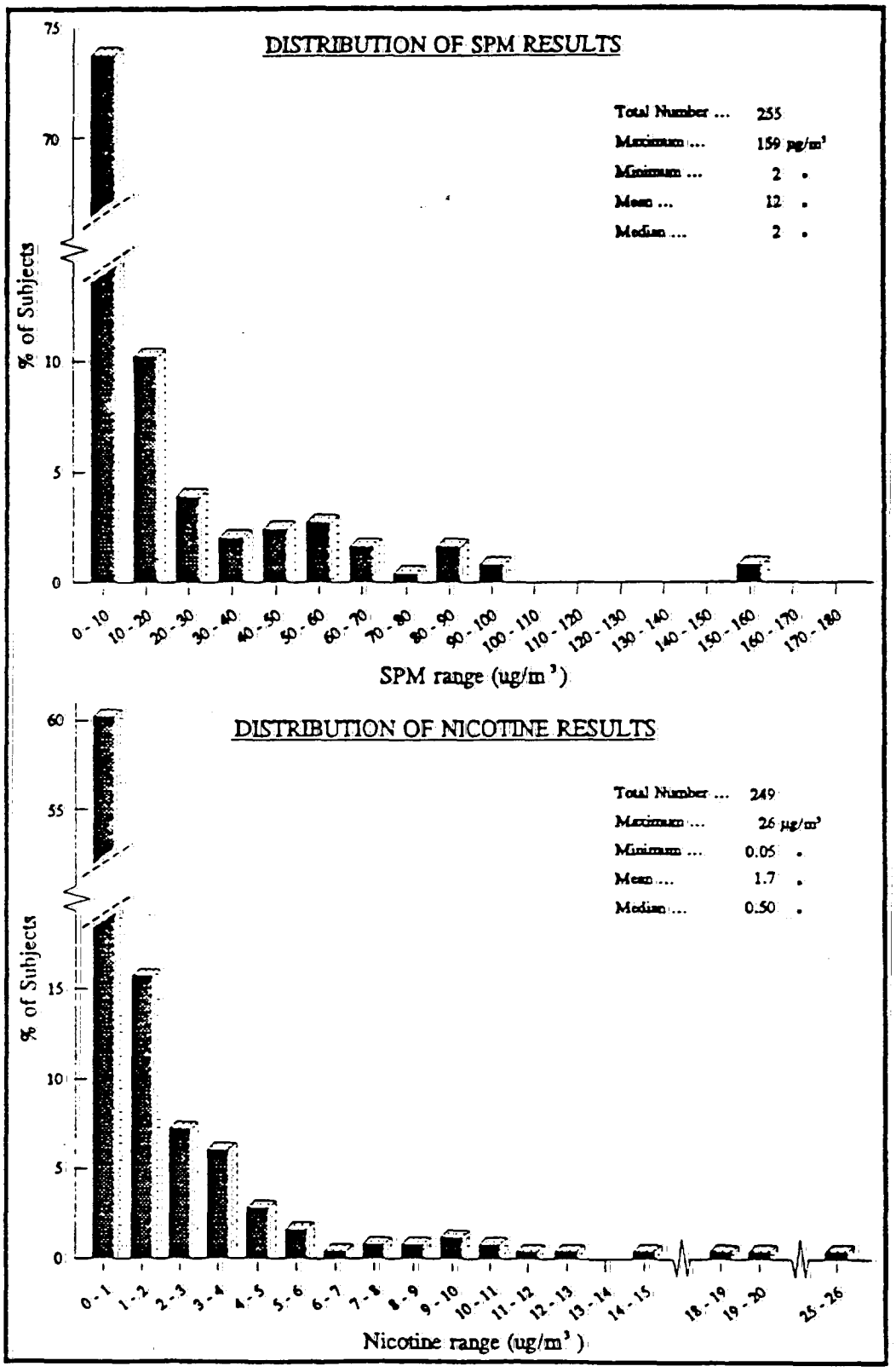
FIGURE 6

DISTRIBUTION OF SPM and NICOTINE RESULTS



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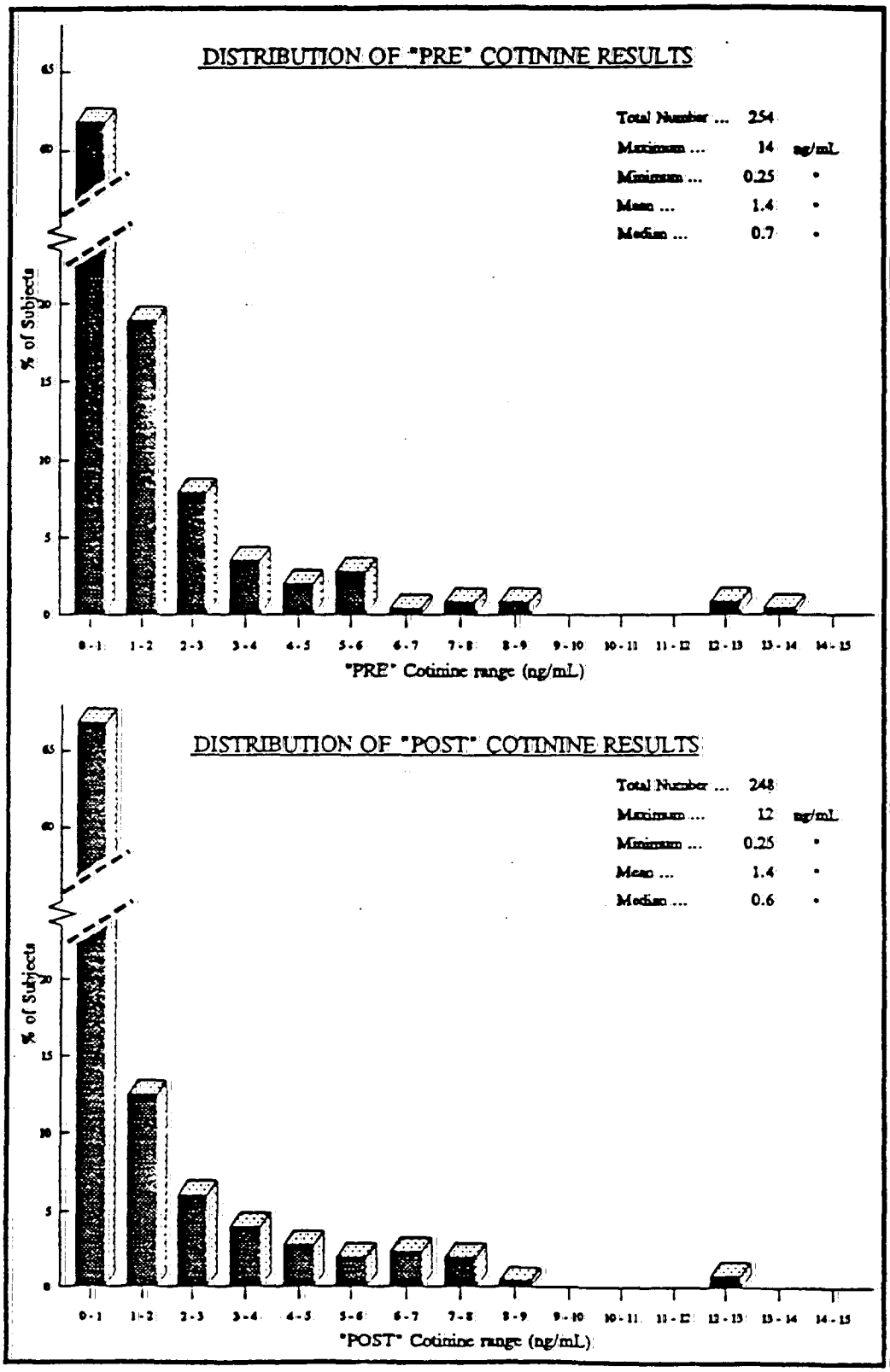
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

DISTRIBUTION OF COTININE RESULTS



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4.9 Objective 2

To assess the contributions to total ETS exposure from the home, the workplace, leisure and travel.

Individual contributions to total ETS exposure from the home, workplace, leisure and travel were assessed by questionnaire and by evaluation of 24 hour measurements on those subjects who reported exposure to ETS from only one of these four sources. Computed estimates for all subjects were also made based on a combination of questionnaire and directly measured data.

4.9.1 Subjective assessment by questionnaire

Figure 8 shows the subjective assessments made by subjects of the percentage contributions of the four sources of ETS exposure to their overall exposure. The figure represents data provided by the 156 subjects who claimed some exposure to ETS during the monitoring period.

Figure 9 shows how these assessments are distributed for the monitoring period.

Figure 10 shows a distribution of assessments by all subjects for the previous six months.

These subjective assessments indicate the ranking of sources of exposure is:

LEISURE > WORK > HOME > TRAVEL

These assessments of relative contributions should be considered in combination with the assessments made by all subjects of their level of exposure from each of the four sources. Figure 11 shows the assessments of level of exposure for each of the four sources by subjects who were exposed from that source but not exclusively.

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Figure 12 shows the assessments of level of exposure for three of the four sources by subjects who were exposed from that source exclusively. There are not enough data on Travel (three subjects) to provide meaningful information in this case.

4.9.2 Direct exposure measurements

Contributions to ETS exposure from the home, workplace, leisure and travel were evaluated for those subjects who reported single source exposure exclusively. These were the only subjects for which information about the single sources of exposure could be estimated directly because most subjects were either exposed to no ETS or exposed to more than one source.

Figure 13 shows the summary for measured exposure levels of SPM and nicotine and the number of subjects involved.

Figures 14 and 15 show how these data are distributed for SPM and nicotine respectively.

Results for the direct measurements indicate that for both SPM and nicotine the ranking is:

HOME > LEISURE > WORK

4.9.3 Computed exposure estimates

In view of the small numbers of subjects in these groups, another approach was used to assess the home, workplace, leisure and travel contributions to total ETS exposure for all subjects.

Each subject's estimate of relative exposure from the four different sources (Question 17) was used in order to distribute the corresponding measured overall exposure throughout the four sources. Where the subjects rated

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their average ETS exposure to be 'none' (Question 15) then the corresponding measured levels were distributed according to the number of hours the subject spent by source (Questions 21 to 24).

Figure 16 shows the summary exposure levels computed on this basis.

It is difficult to assess the relative ETS contributions on the basis of median results as the values are so low. However, the mean results for the measured and computed data sets suggest that the magnitude of contributions is:

HOME > LEISURE > WORK > TRAVEL

Part of the explanation for this ranking is undoubtedly the amounts of time spent in these situations. For most people, the majority of their time is spent at home whereas travel occupies only a small part of their time.

It is interesting that the ranking of the directly measured exposures is different from the ranking perceived by the subjects. One possible explanation for this is that subjects have based their judgements on the relative ETS levels in the four situations while neglecting the amount of time spent in these situations.

The directly measured results indicate that the ranking of relative contributions to total ETS exposure is HOME > LEISURE > WORK > TRAVEL. Subjective assessments appear to overestimate the contributions from leisure and the workplace to total exposure. Both subjective assessment and direct measurements indicate that travel makes a very small contribution to overall exposure.

The large majority of subjects regard the exposure level from each of the four sources as 'none' or 'low'. This is consistent with the direct measurements of exposure.

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FIGURE 8

PERCENT RELATIVE CONTRIBUTIONS TO OVERALL ETS EXPOSURE

(SUBJECTIVE)

	Monitoring period	Last six months
Home	27.8	19.8
Work	31.5	29.4
Leisure	35.1	46.3
Travel	5.7	4.7

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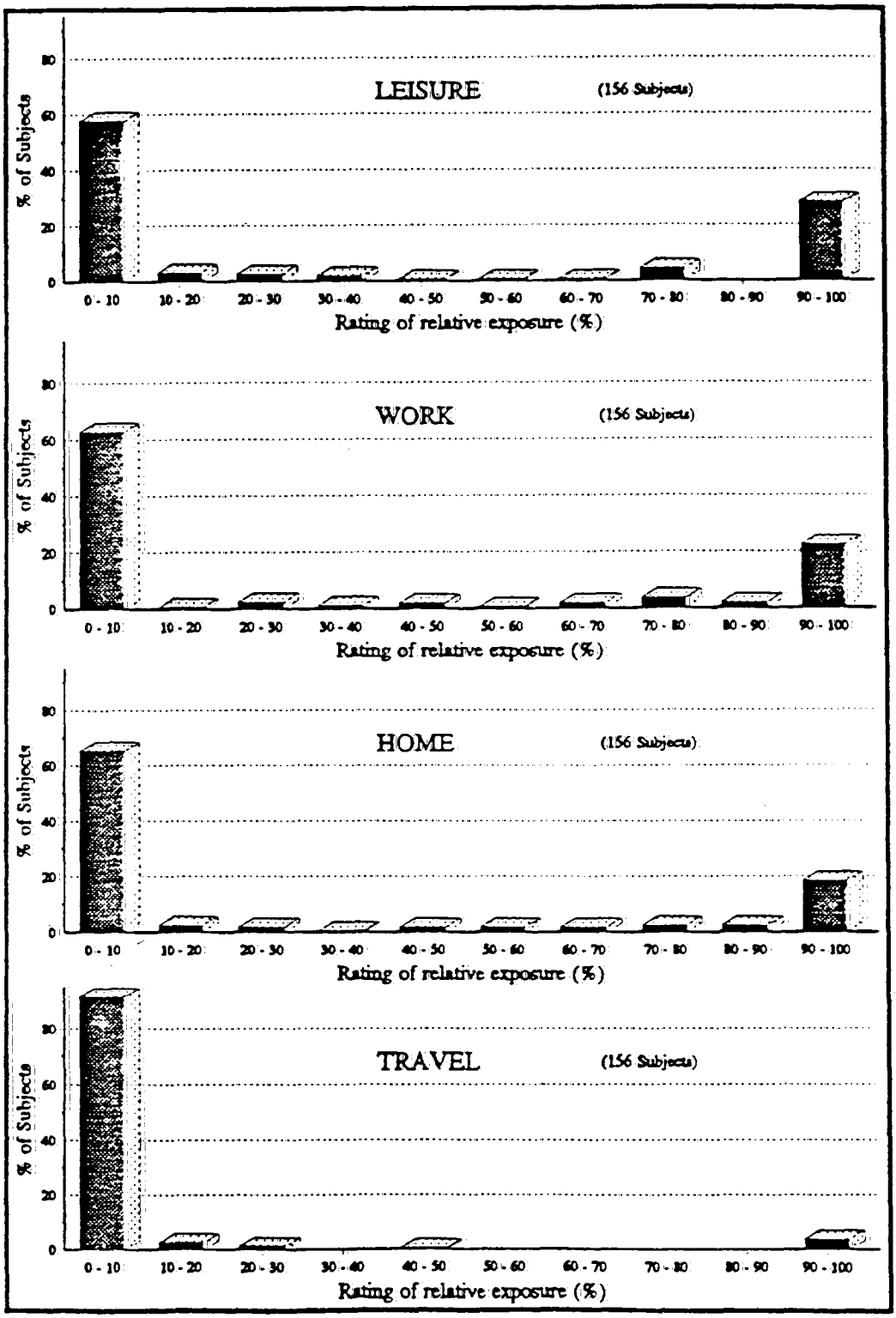
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 9

SUBJECTIVE ASSESSMENT OF RELATIVE PERCENTAGE ETS EXPOSURE BY SOURCE (MONITORING PERIOD)



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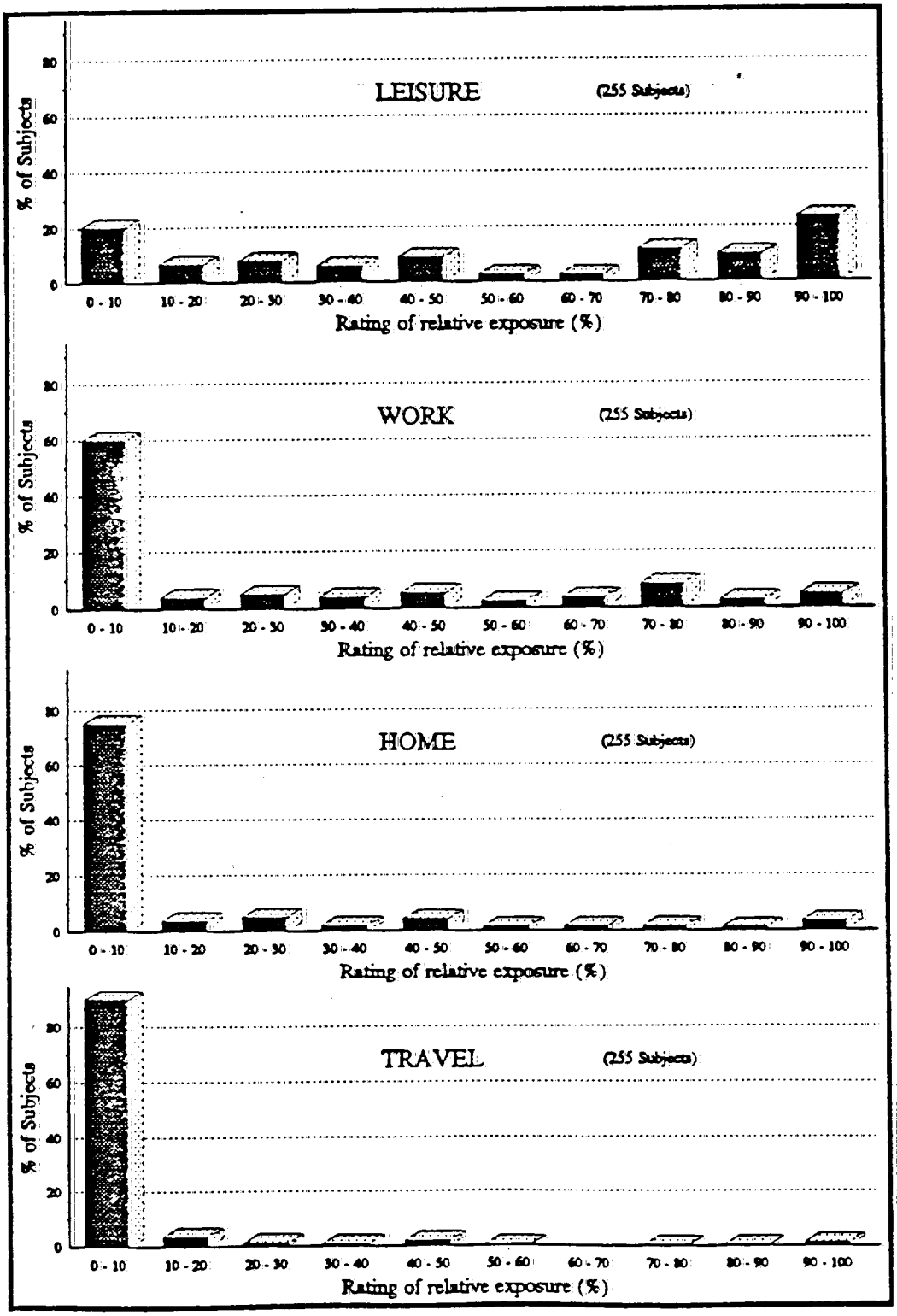
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 10

SUBJECTIVE ASSESSMENT OF RELATIVE PERCENTAGE ETS EXPOSURE BY SOURCE (LAST 6 MONTHS)



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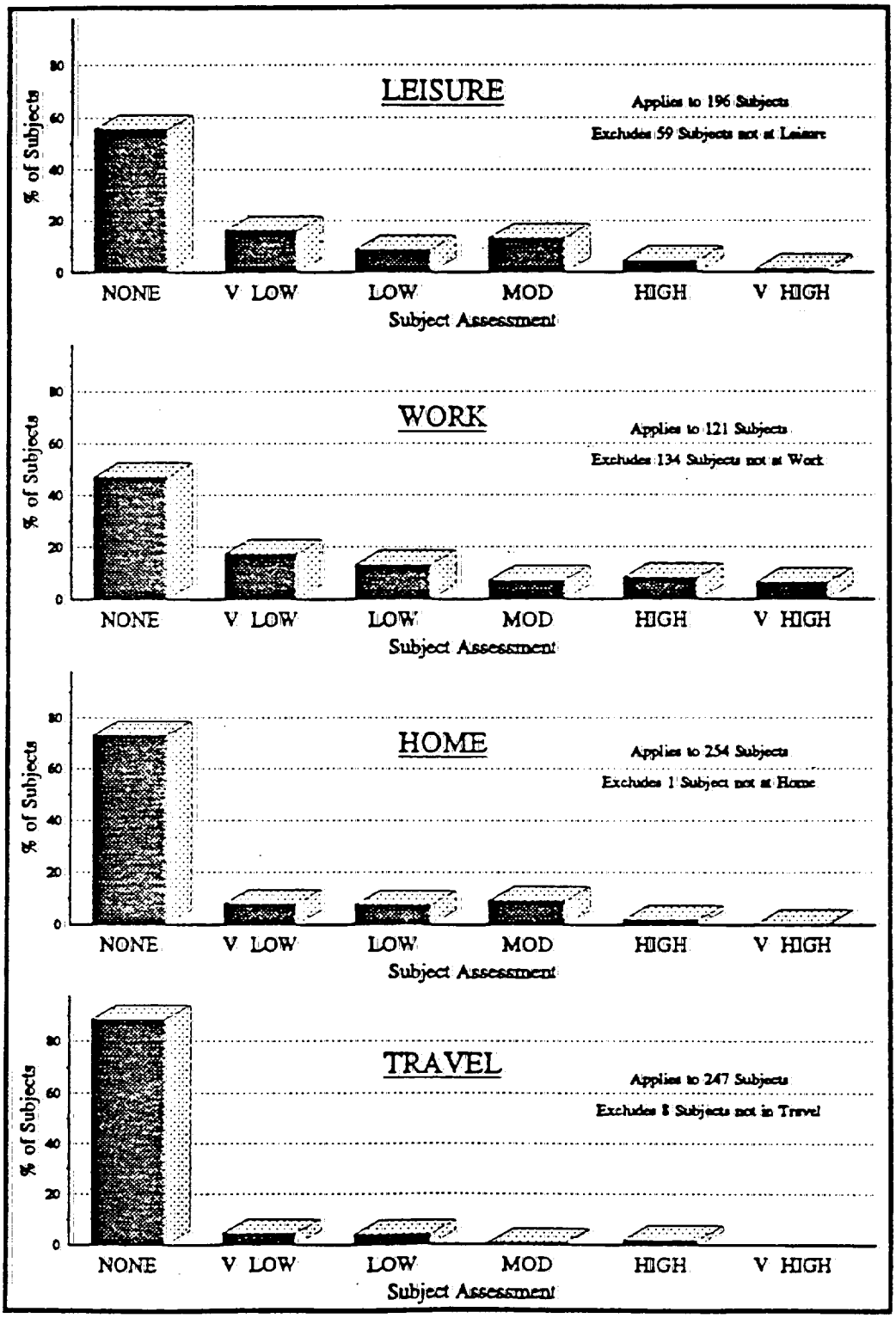
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 11

SUBJECTIVE ASSESSMENT OF ETS EXPOSURE BY SOURCE DURING MONITORING PERIOD



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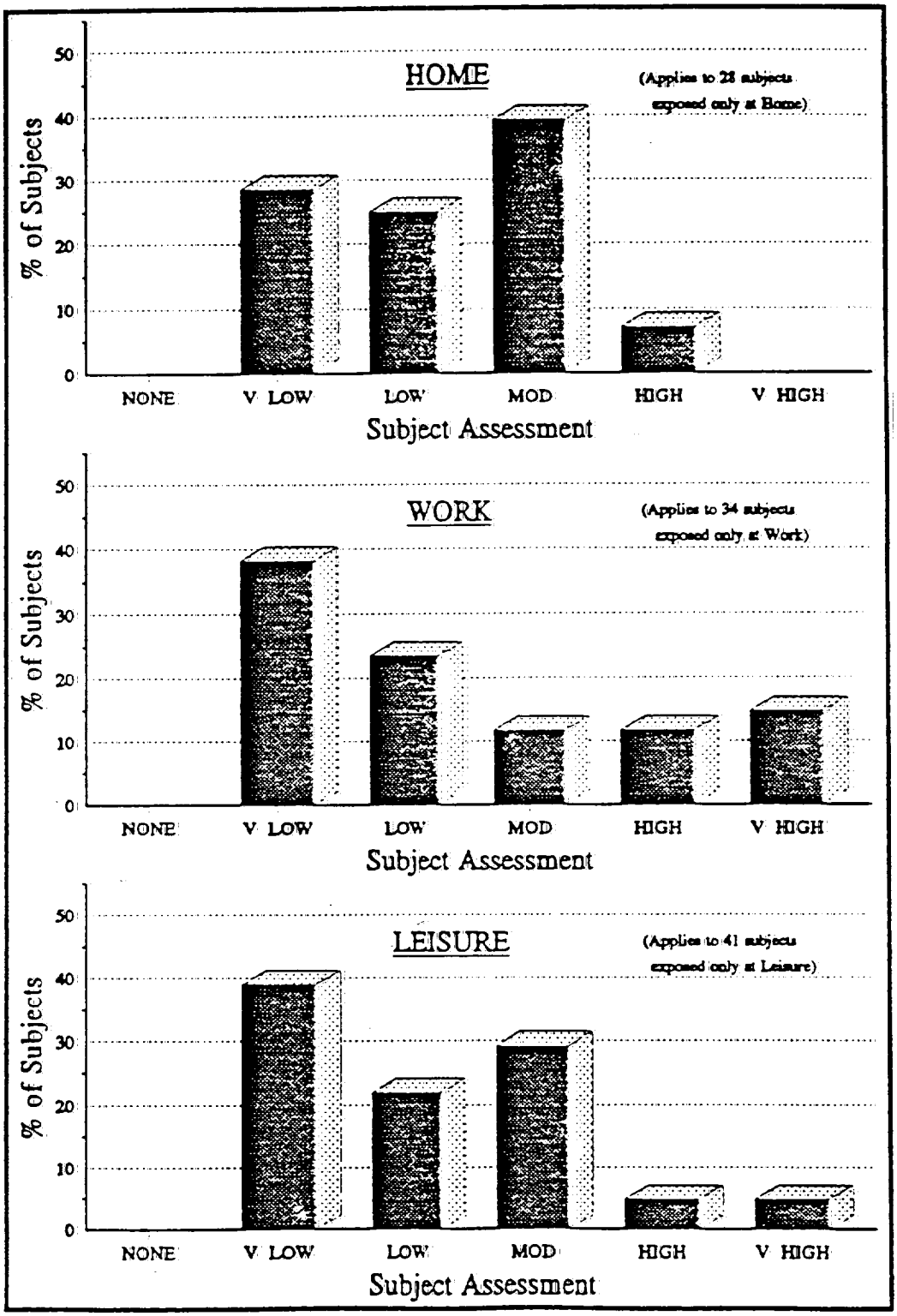
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 12

SUBJECTIVE ASSESSMENT OF ETS EXPOSURE DURING MONITORING PERIOD (ONLY "SINGLE SOURCE" SUBJECTS)



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Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 13

MEASURED EXPOSURE AT HOME, WORKPLACE, LEISURE AND TRAVEL

		Number	Maximum	Minimum	Mean	Median
Home		28	70	2	18	7
Workplace	SPM	34	44	2	6	2
Leisure	$\mu g/m^3$	41	64	2	10	2
Travel		3	2	2	2	2
Home		28	11	0.05	2	1.2
Workplace	Nicotine	34	5.6	0.05	1.1	0.57
Leisure	$\mu g/m^3$	39	9.2	0.05	1.4	0.72
Travel		3	0.63	0.21	0.4	0.35

These results are for subjects reporting exposure from only one of the four sources.

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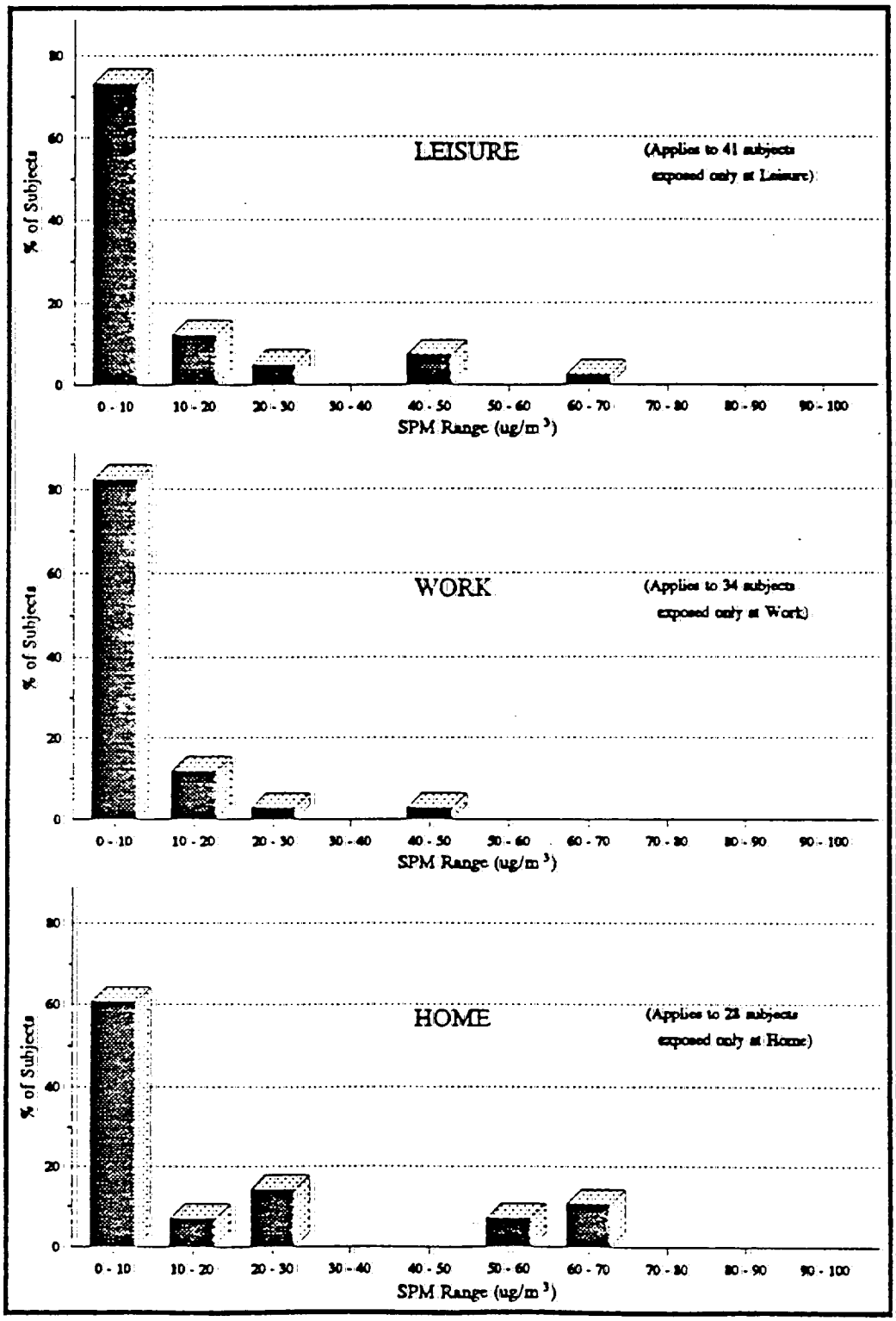
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 14

DISTRIBUTION OF SPM RESULTS BY SOURCE

(SUBJECTS ASSESSING EXPOSURE AS SINGLE SOURCE)



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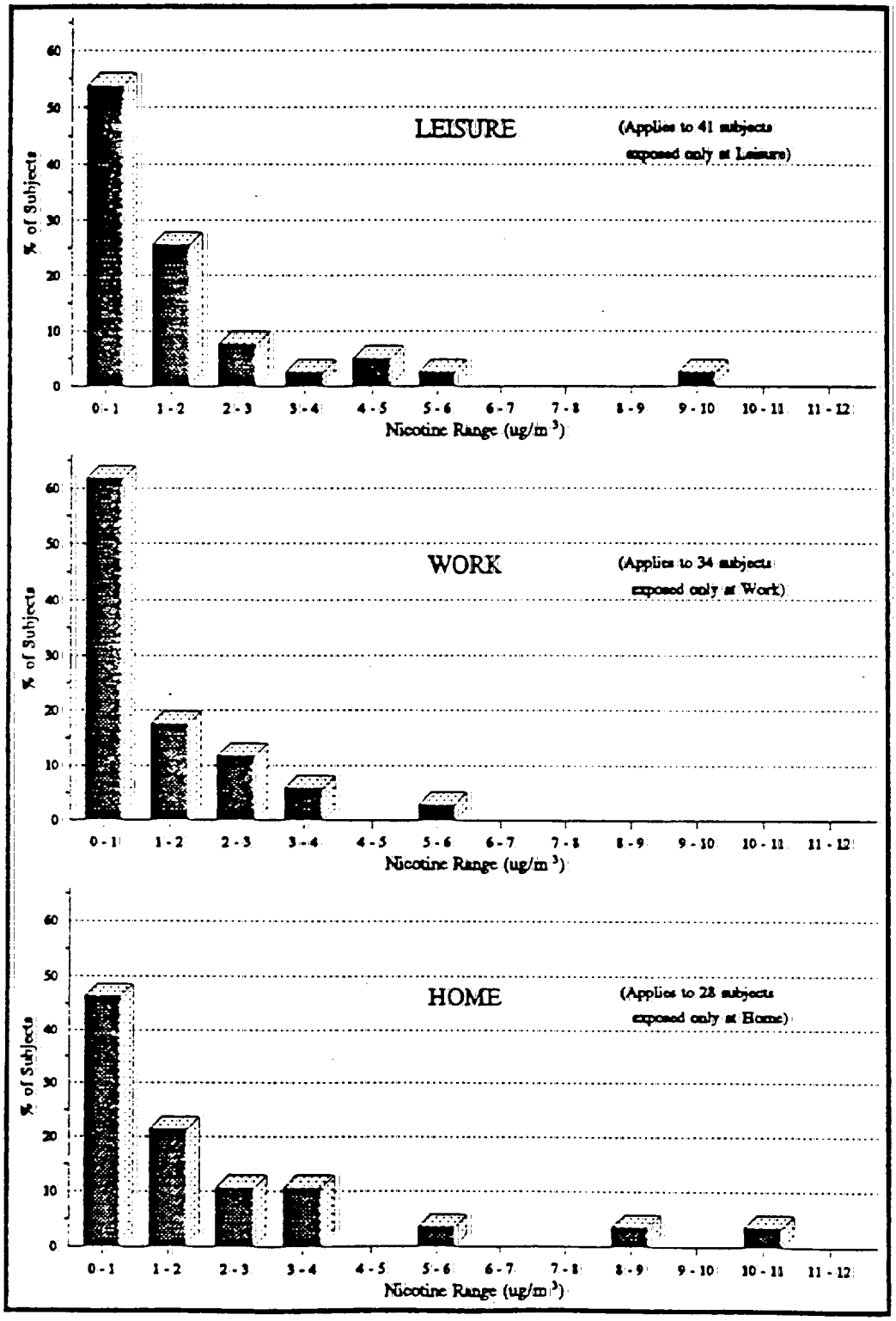
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 15

DISTRIBUTION OF NICOTINE RESULTS BY SOURCE

(SUBJECTS ASSESSING EXPOSURE AS SINGLE SOURCE)



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Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 16

"COMPUTED" ESTIMATES FOR KEY ANALYTES BY SOURCE

	Maximum	Mean	Median	
Home	107.2	5.73	1.46	
Work	78.6	2.60	0.00	SPM
Leisure	11.0	0.41	0.00	$\mu g/m^3$
Travel	151.2	3.75	0.08	
Home	15.5	0.76	0.04	
Work	9.7	0.39	0.00	Nicotine
Leisure	2.1	0.06	0.00	$\mu g/m^3$
Travel	24.3	0.54	0.00	

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Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

4.10 Objective 3

To assess whether non-smokers who are married to smokers have significantly higher exposures to ETS than non-smokers married to non-smokers.

To address this objective the 255 subjects were divided into three groups as follows:

	Number in group
Subjects with no spouse or partner	74
Subjects with a non-smoking spouse or partner	133
Subjects with a smoking spouse or partner	48

4.10.1 Subjective assessment by questionnaire

Figure 17 shows the subjective assessments of 24 hour exposure made by the three groups.

Although there is clearly an overlap in the assessments made by the three groups the results suggest that the ranking of exposure is

SMOKING SPOUSE OR PARTNER > NO SPOUSE OR PARTNER > NON-SMOKING SPOUSE OR PARTNER

4.10.2 Direct measurements and salivary cotinine levels

The directly measured exposure levels and the salivary cotinine results for these three groups of subjects are summarised in Figure 18 and Figure 20 respectively.

Figure 19 shows the distributions of the SPM results for these subject groups. These show a similar pattern to the subjective assessments.

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Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

Again, the ranking of exposure levels is:

SMOKING SPOUSE OR PARTNER > NO SPOUSE OR PARTNER > NON-SMOKING SPOUSE OR PARTNER

Epidemiological studies related to ETS exposure have used the criterion of a spouse that smokes as an index of ETS exposure. The mean exposure levels for subjects with a smoking spouse or partner were greater than for those with a non-smoking spouse or partner. However, the distributions of results show that there is not a clear distinction between the two groups and that there is a substantial overlap between the ranges in both the subjective and the measured results. Furthermore 46% of subjects with a smoking spouse/partner assessed their ETS exposure as 'none' or 'low'. This is supported by direct measurements. Also, approximately 30% of subjects with a smoking spouse/partner assessed leisure or work as their principal source of exposure.

Clearly the criterion of a smoking spouse or partner should not be used, without supplementary evidence, when assessing ETS exposure of individual subjects.

Statistical evaluation of the results using non parametric methods is shown in Figure 21. The results show that the differences in the ETS exposure levels for these subject groups are significant. There were, however, no significant differences in PAS exposure between these groups.

The exposure levels of the group of subjects with a smoking spouse or partner is significantly higher than that of subjects with non-smoking spouses or partners. However there is considerable variation in the exposure of individual subjects within these groups as well as overlap between the groups. It is recommended that spouse or partner smoking status should only be used in combination with supplementary information when assessing ETS exposure.

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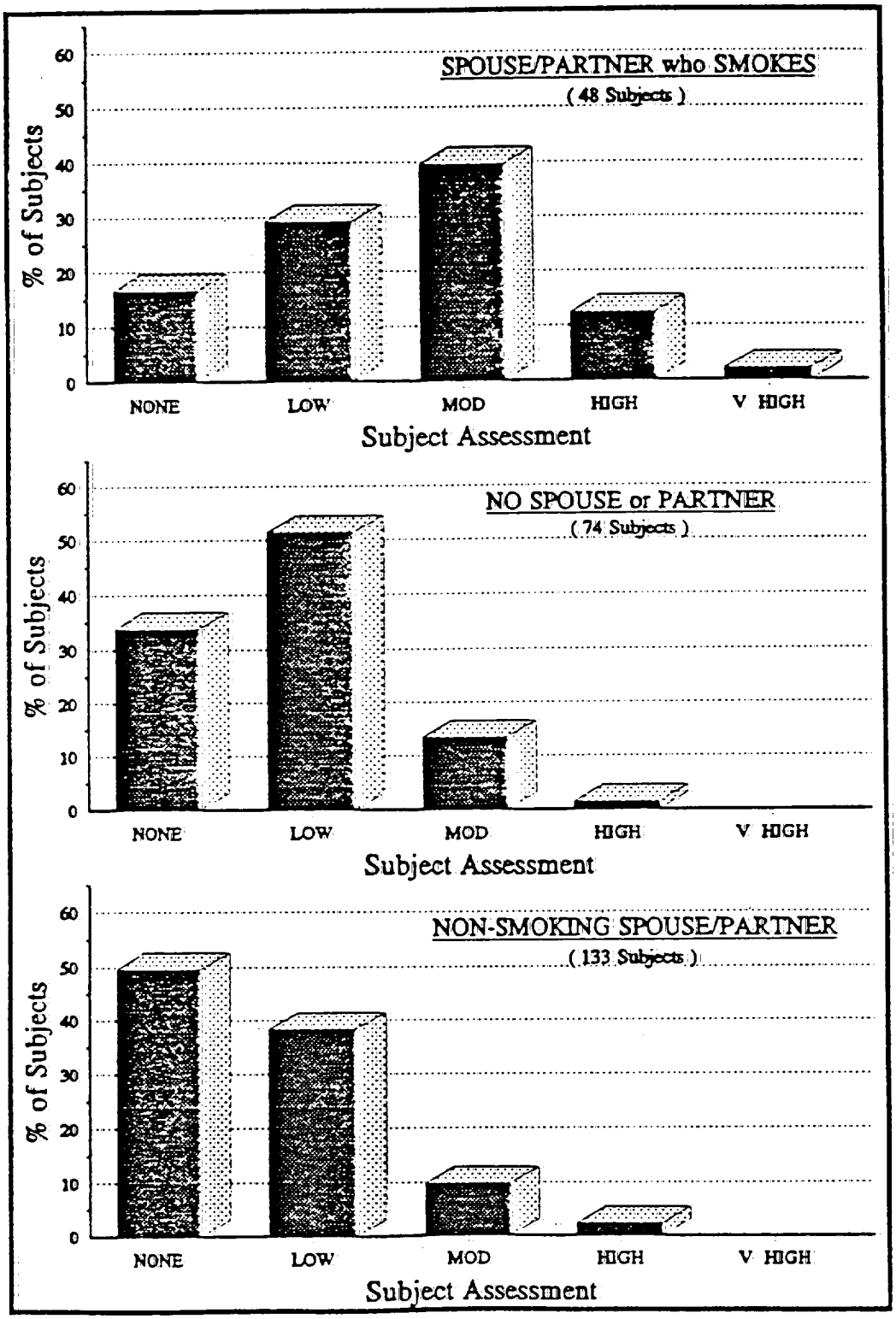
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 17

SUBJECTIVE ASSESSMENT OF AVERAGE ETS EXPOSURE ACCORDING TO SPOUSE'S SMOKING HABITS



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Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 18

SUMMARY OF PAS, SPM AND NICOTINE LEVELS FOUND BY CLASSIFICATION OF SPOUSE OR PARTNER

		Number	Minimum	Maximum	Mean	Median
Overall	PAS ($\mu g/m^3$)	255	20	1219	179	142
NS Partner	"	133	20	995	166	129
SM Partner	"	48	48	1219	219	161
No Partner	"	74	35	539	178	143
Overall	SPM ($\mu g/m^3$)	255	2	159	12	2
NS Partner	"	133	2	159	7	2
SM Partner	"	48	2	153	29	17
No Partner	"	74	2	97	12	2
Overall	Nic ($\mu g/m^3$)	249	0.05	26	1.7	0.50
NS Partner	"	130	0.05	26	1.1	0.28
SM Partner	"	47	0.05	18	4.0	2.5
No Partner	"	72	0.05	19	1.5	0.55

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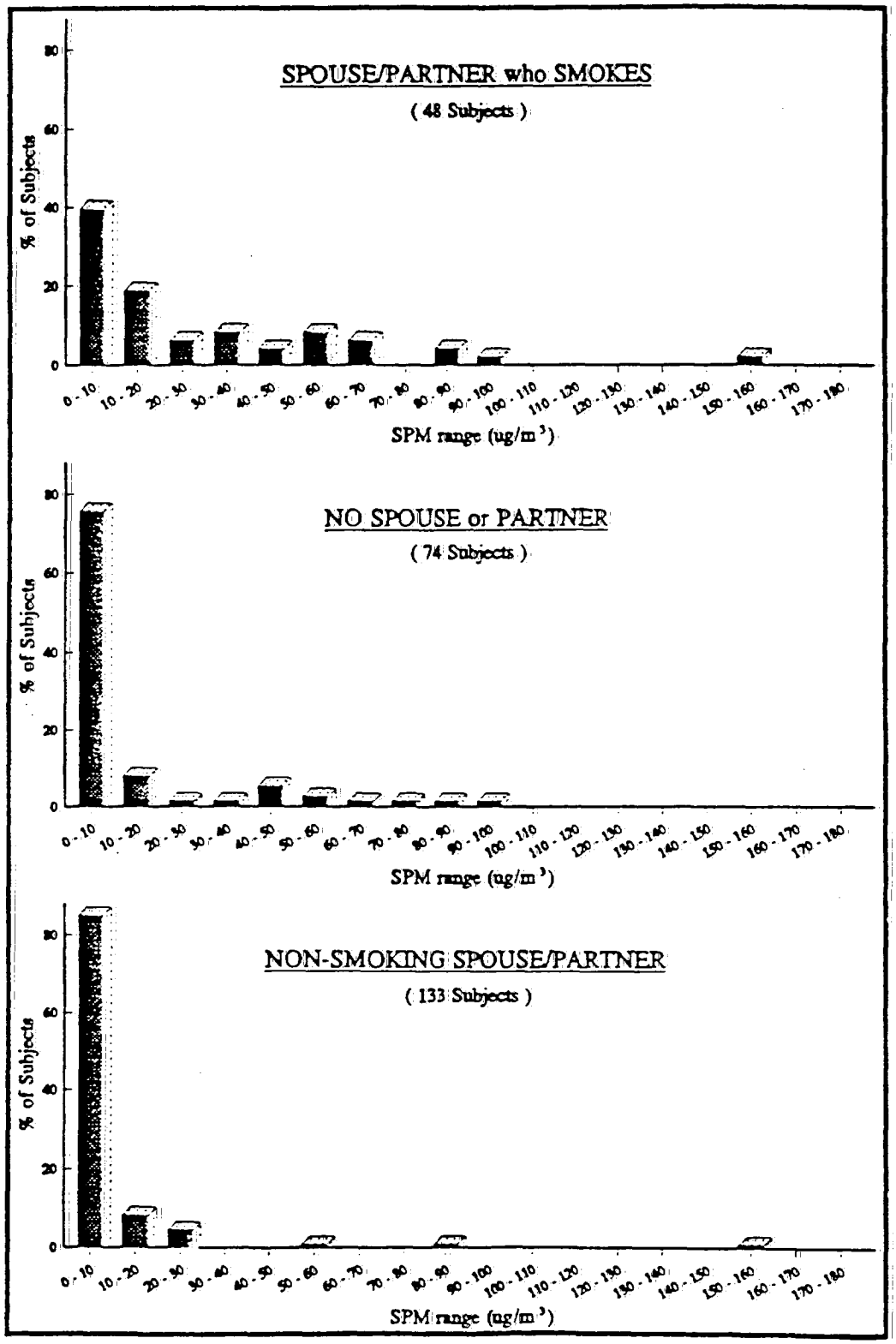
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 19

DISTRIBUTION OF SPM RESULTS ACCORDING TO TO SPOUSE'S SMOKING HABITS



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Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 20

SUMMARY OF PRE AND POST COTININE LEVELS FOUND BY CLASSIFICATION OF SPOUSE OR PARTNER

		Number	Minimum	Maximum	Mean	Median
Overall	Pre Cotinine (ng/mL)	254	0.25	14	1.4	0.7
NS Partner	"	132	0.25	8.2	0.83	0.25
SM Partner	"	48	0.25	13	2.3	1.4
NO Partner	"	74	0.25	14	1.8	1.0
Overall	Post Cotinine (ng/mL)	248	0.25	12	1.4	0.6
NS Partner	"	128	0.25	12	0.99	0.25
SM Partner	"	47	0.25	8.1	2.2	1.5
NO Partner	"	73	0.25	12	1.7	0.6

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Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 21

SUMMARY OF STATISTICAL DIFFERENCES

	NS vs SM	NS vs NP	SM vs NP
SPM	***	**	***
Nicotine	***	*	***
Pre-cotinine	***	***	**
Post-cotinine	***	**	**

* $P < 0.05$
** $P < 0.01$
*** $P < 0.001$
NS = Non smoking spouse or partner
SM = Smoking spouse or partner
NP = No spouse or partner

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Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

4.11 Objective 4

To compare questionnaires, direct measurements and salivary cotinine levels as methods of assessing exposure to ETS.

To meet this objective various direct measurements, using the personal monitor, will be compared with each other, with the salivary cotinine levels and with the subjective assessments. Direct measurements by personal monitoring are assumed to provide the most reliable estimate of ETS exposure.

4.11.1 Subjective assessments compared with Direct Measurements

Figure 22 shows the relationship between subjects' assessments of their ETS exposure during the monitoring period and the corresponding direct measurements of SPM and nicotine.

As expected, there is a tendency for measured exposure to increase with higher subjective assessments. The majority of subjects can estimate an exposure of 'none' quite well, but there is a considerable variation between direct measurements at higher assessed levels and considerable overlap in the measured exposures for the various grades of subjective assessments.

Some subjects reported their exposure as 'high' but had less directly measured exposure to ETS than some subjects who reported their exposure as 'low'. Clearly, an individual's ETS exposure cannot reliably be estimated by a simple subjective question about levels of exposure.

4.11.2 Subjective assessments compared with salivary cotinine measurements

Figure 23 shows the relationship between subjects' assessments of their ETS exposure during the monitoring period and the corresponding measured levels of salivary cotinine at the start and end of the monitoring period. The relationships for pre and post cotinine levels are similar.

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Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

Again there is a trend towards an increase in measured exposure with higher subjective assessments.

It should be noted that some subjects had relatively high levels of salivary cotinine even though they reported their ETS exposure as 'none'. Furthermore, some subjects had low cotinine levels when they reported their ETS exposure as 'moderate' or 'high'. These findings raise doubts concerning the use of salivary cotinine measurements at low levels for ETS exposure assessment. These concerns have also been expressed by other authors (Proctor et al 1991).

4.11.3 Salivary cotinine levels compared with direct measurements

Figures 24A and B are scatter diagrams of measured exposure to SPM against salivary cotinine level with logarithmic and linear plots respectively. Best fit straight lines are drawn in each case.

There is very poor correlation between these two methods of assessing ETS exposure with R-square values of 0.06 and 0.14 for pre and post cotinine respectively.

Figures 25A and B are scatter diagrams of measured exposure to nicotine against salivary cotinine level with logarithmic and linear plots respectively.

The R-square values are 0.07 and 0.13 for pre and post-cotinine respectively.

The poor correlation is surprising because it was expected that salivary cotinine levels would be dependent on exposure to nicotine.

Some subjects who had been exposed to reasonably high levels of SPM and nicotine had no detectable salivary cotinine. Other subjects who had not

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been exposed to any measurable quantity of nicotine had relatively high levels of salivary cotinine. These poor correlations of salivary cotinine level with measured exposure to SPM and nicotine cast further doubt on the value of salivary cotinine measurements.

4.11.4 Comparison of direct measurements

Figures 26A and B are plots of SPM values against nicotine values and against PAS values. Again the logarithmic plots (A) and linear plots (B) are shown with best fit straight lines. The R-square for nicotine = 0.66 and for PAS = 0.04.

Nicotine and SPM are generated together and there is moderate correlation between them. However, nicotine is known not to be associated with ETS particles and the ratio of nicotine to ETS particles changes as a function of dilution and time (Nelson et al 1992).

SPM levels are not expected to be related to PAS and this is shown to be the case on this study.

Figure 27A and B are plots of SPM values against UVPM values and against FPM values with logarithmic and linear plots respectively. The R-square values are 0.19 for UVPM and 0.46 for FPM which indicates a limited correlation with SPM. However, there appears to be a much better correlation for many of the results, but this is detracted from by high results for UVPM or FPM when SPM is low. This illustrates the lack of specificity of the UV and fluorescence measurements.

Figure 28 summarises the comparison of cotinine and direct measurements and shows only moderate correlation for SPM with both nicotine and FPM.

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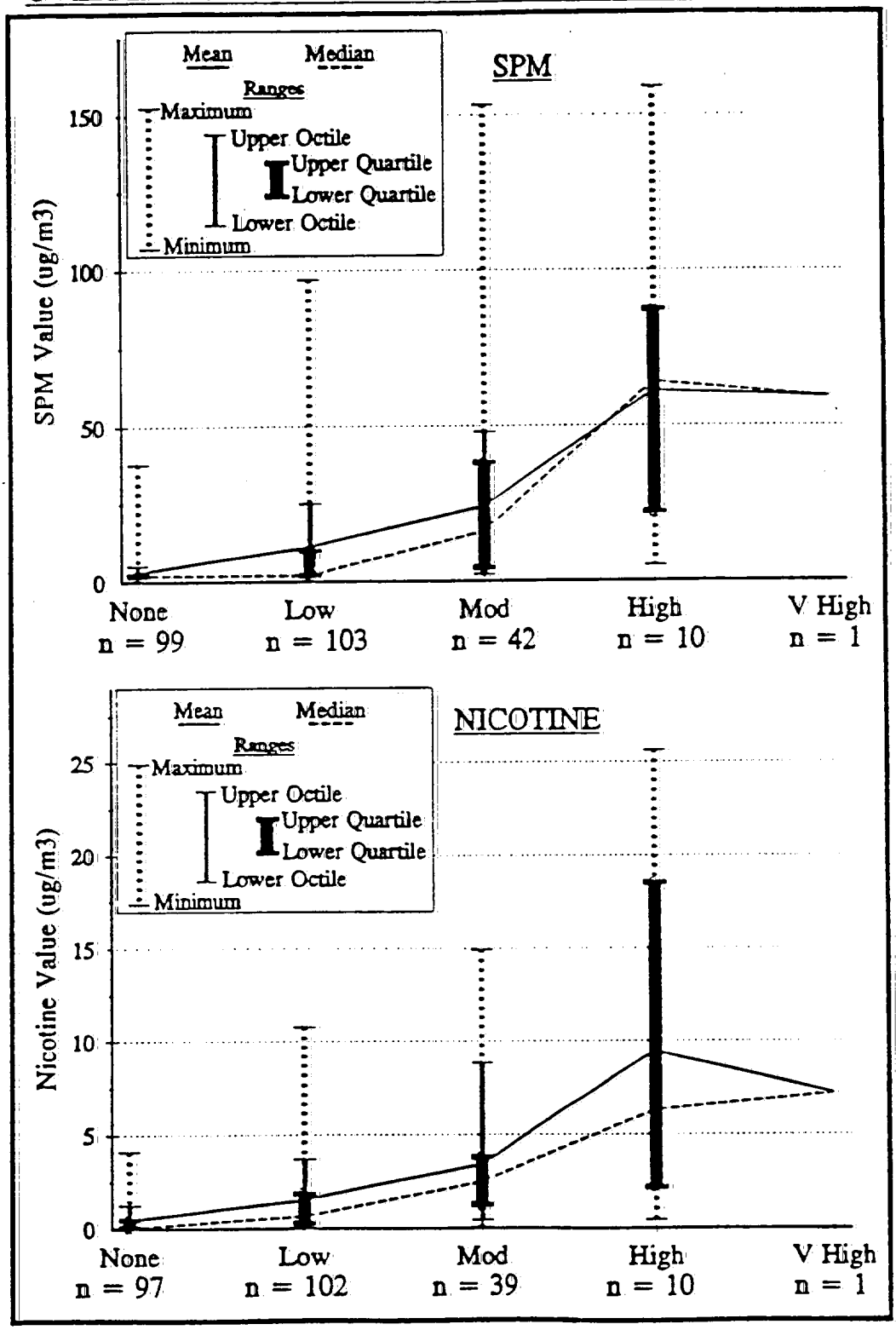
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 22

CORRELATION OF SPM and NICOTINE RESULTS AGAINST OVERALL SUBJECTIVE ASSESSMENT OF ETS EXPOSURE



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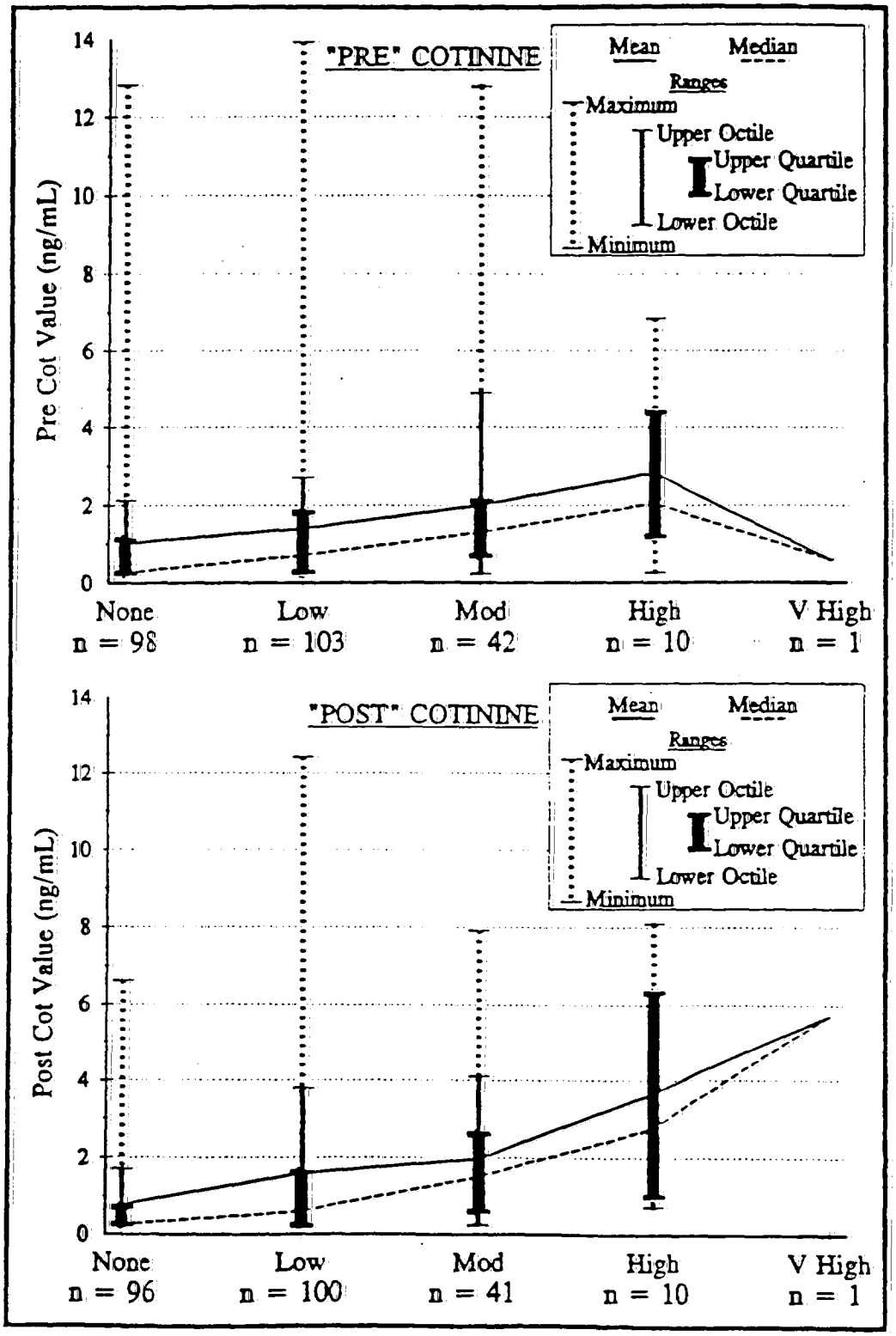
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 23

CORRELATION OF COTININE RESULTS AGAINST OVERALL SUBJECTIVE ASSESSMENT OF ETS EXPOSURE



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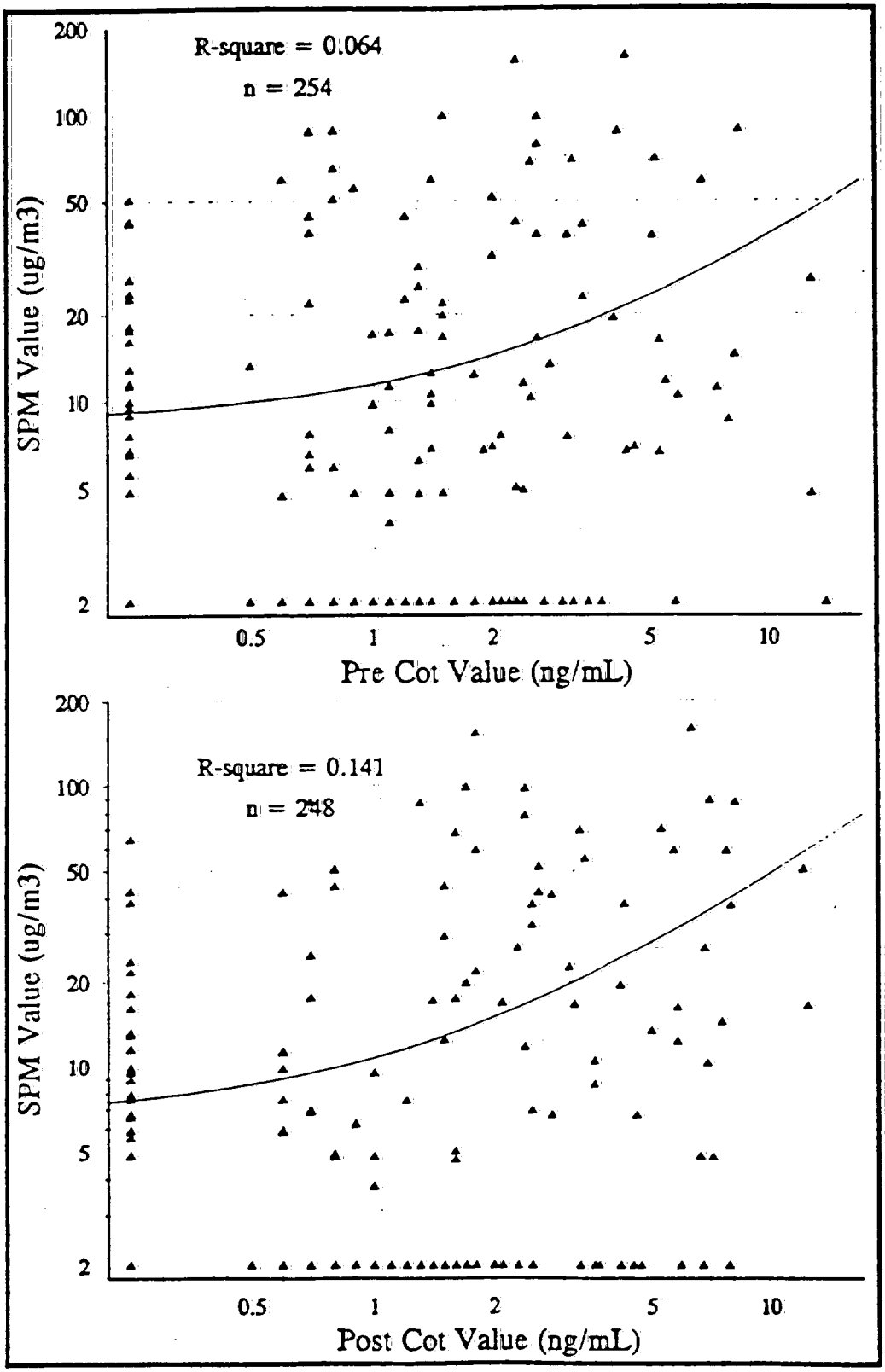
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 24A

CORRELATION OF SPM RESULTS WITH COTININE



Logarithmic plot

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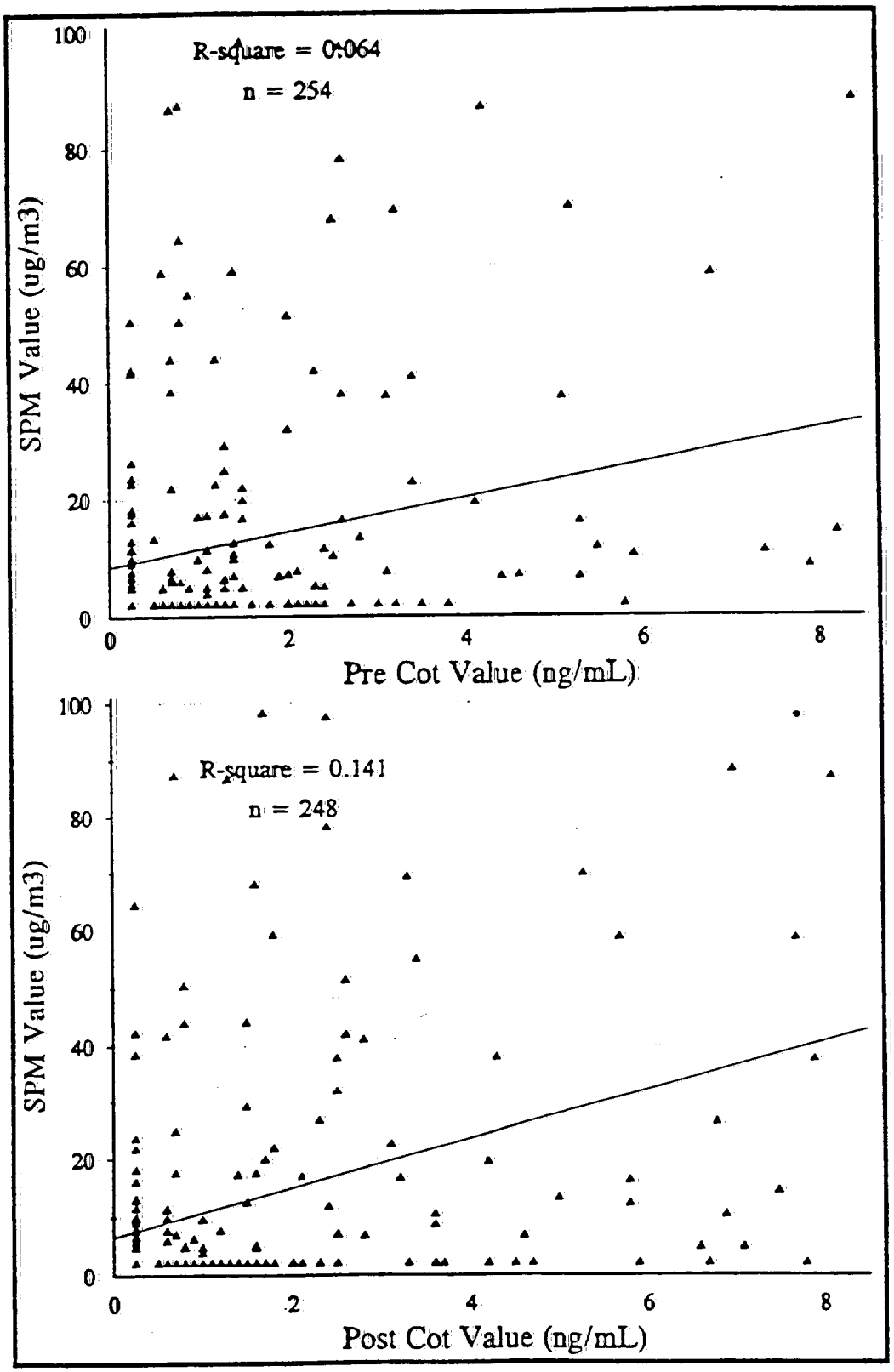
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 24B

CORRELATION OF SPM RESULTS WITH COTININE



Linear plot

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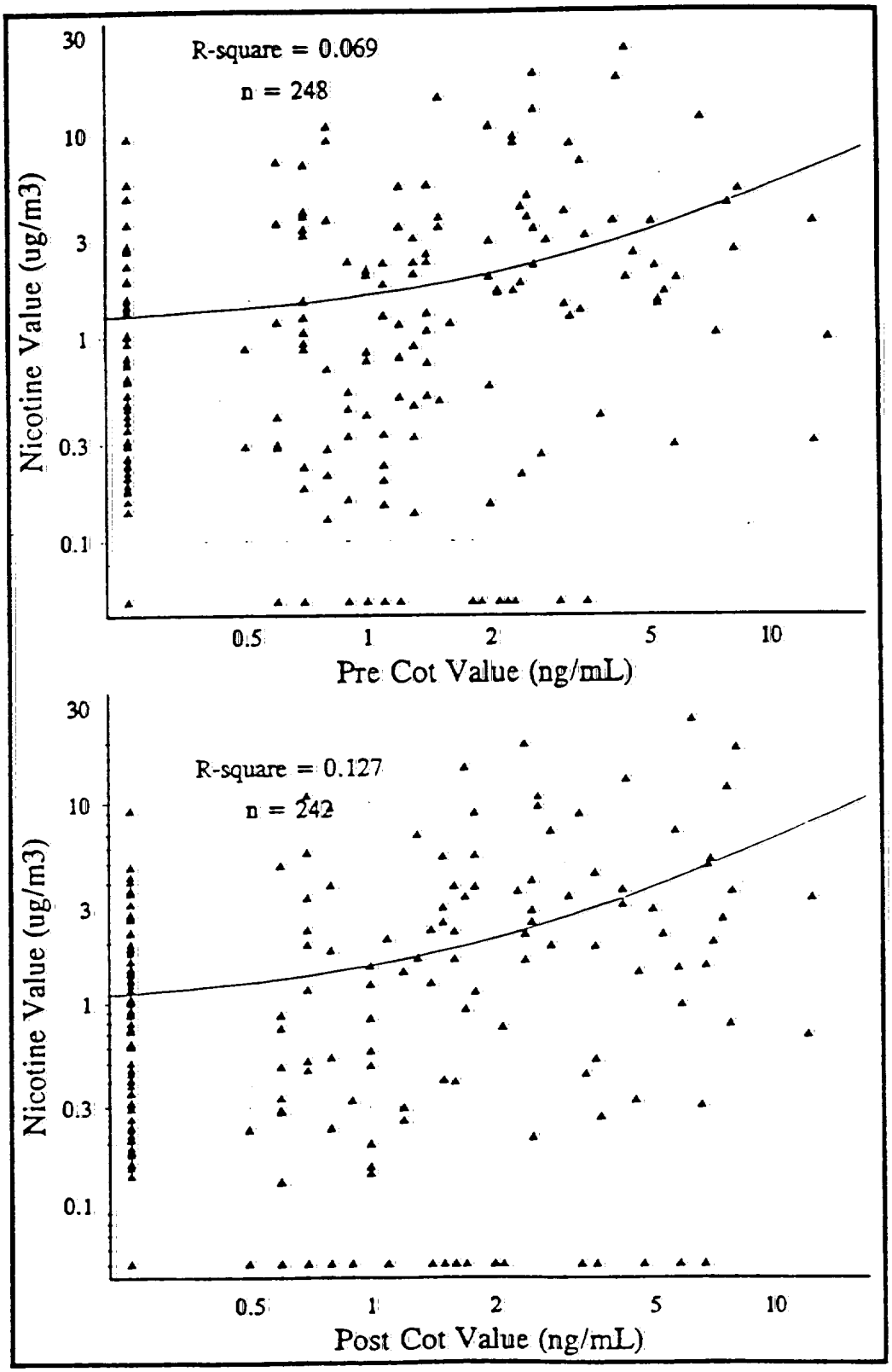
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 25A

CORRELATION OF NICOTINE RESULTS WITH COTININE



Logarithmic plot

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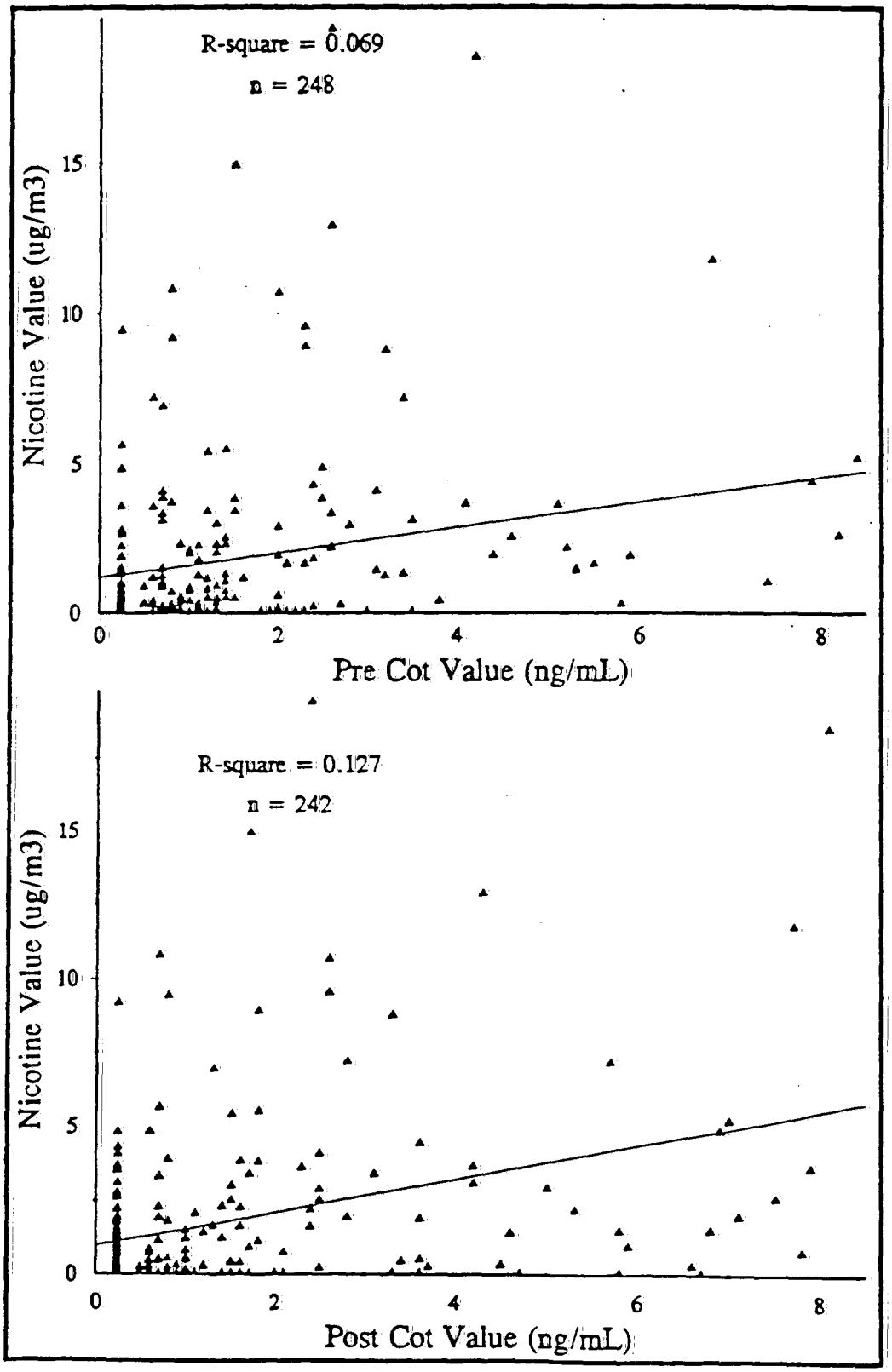
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 25B

CORRELATION OF NICOTINE RESULTS WITH COTININE



Linear plot

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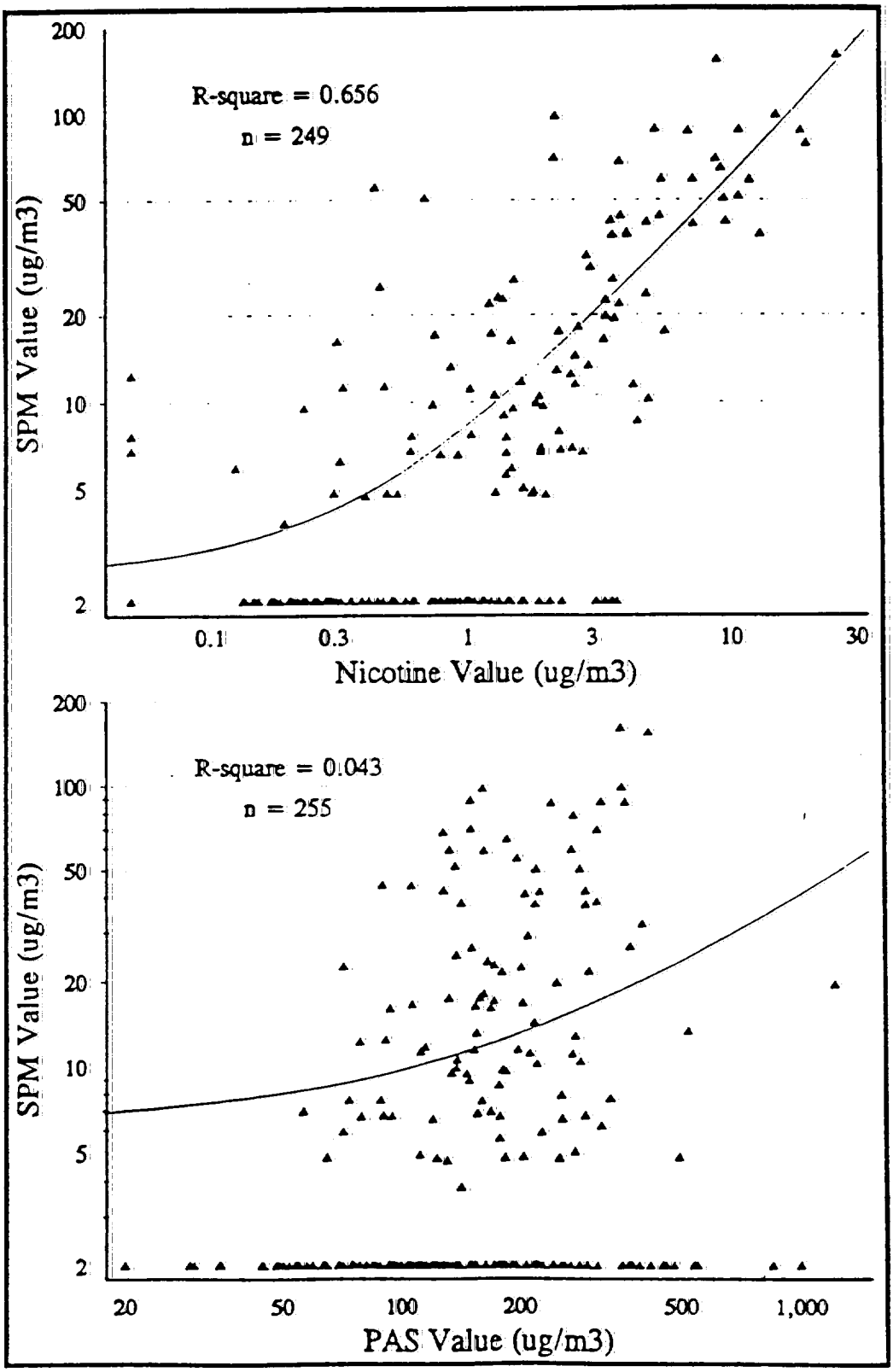
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 26A

CORRELATION OF SPM RESULTS WITH NICOTINE and PAS



Logarithmic plot

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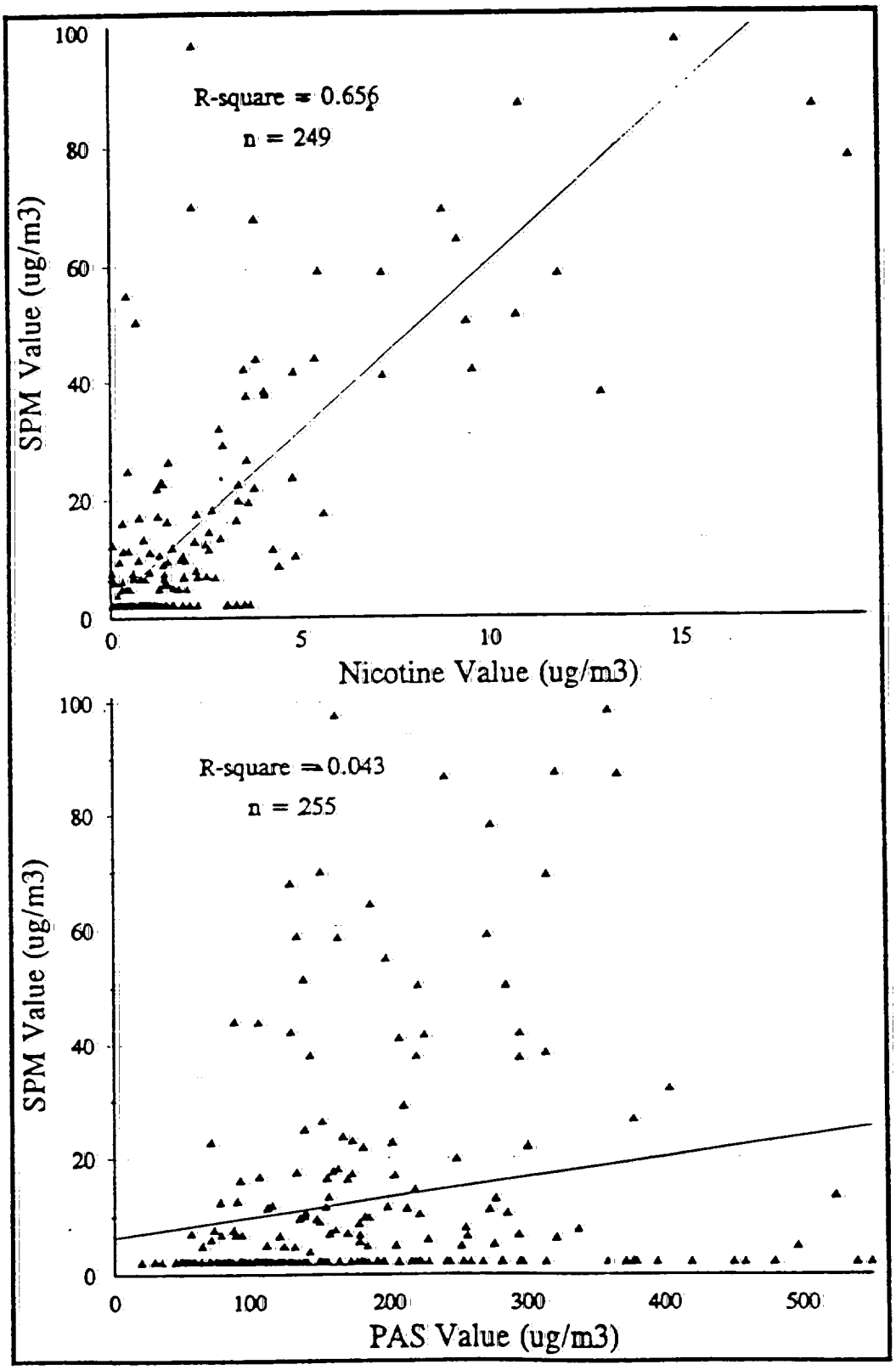
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 26B

CORRELATION OF SPM RESULTS WITH NICOTINE and PAS



Linear plot

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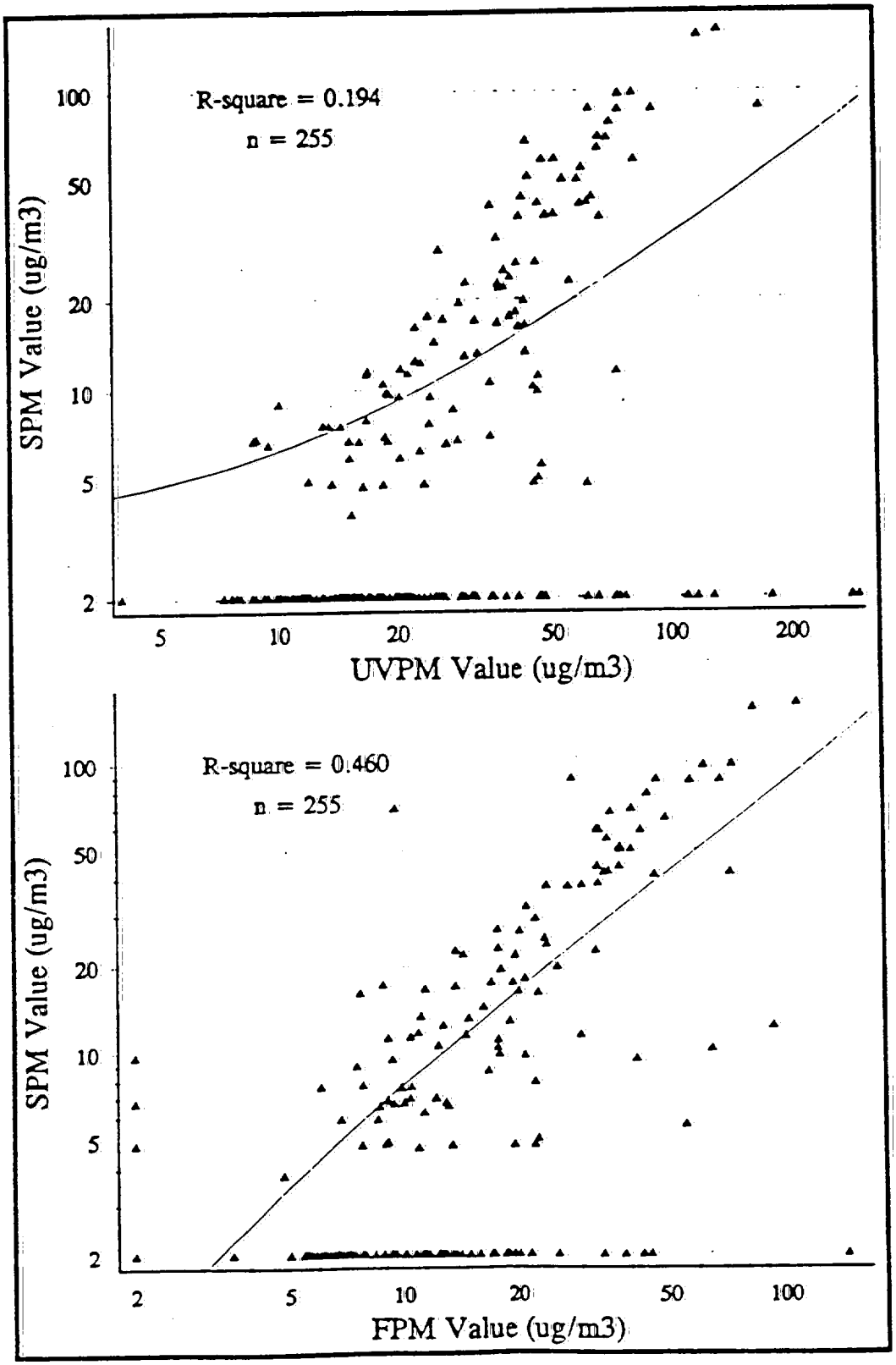
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 27A

CORRELATION OF SPM RESULTS WITH UVPM and FPM



Logarithmic plot

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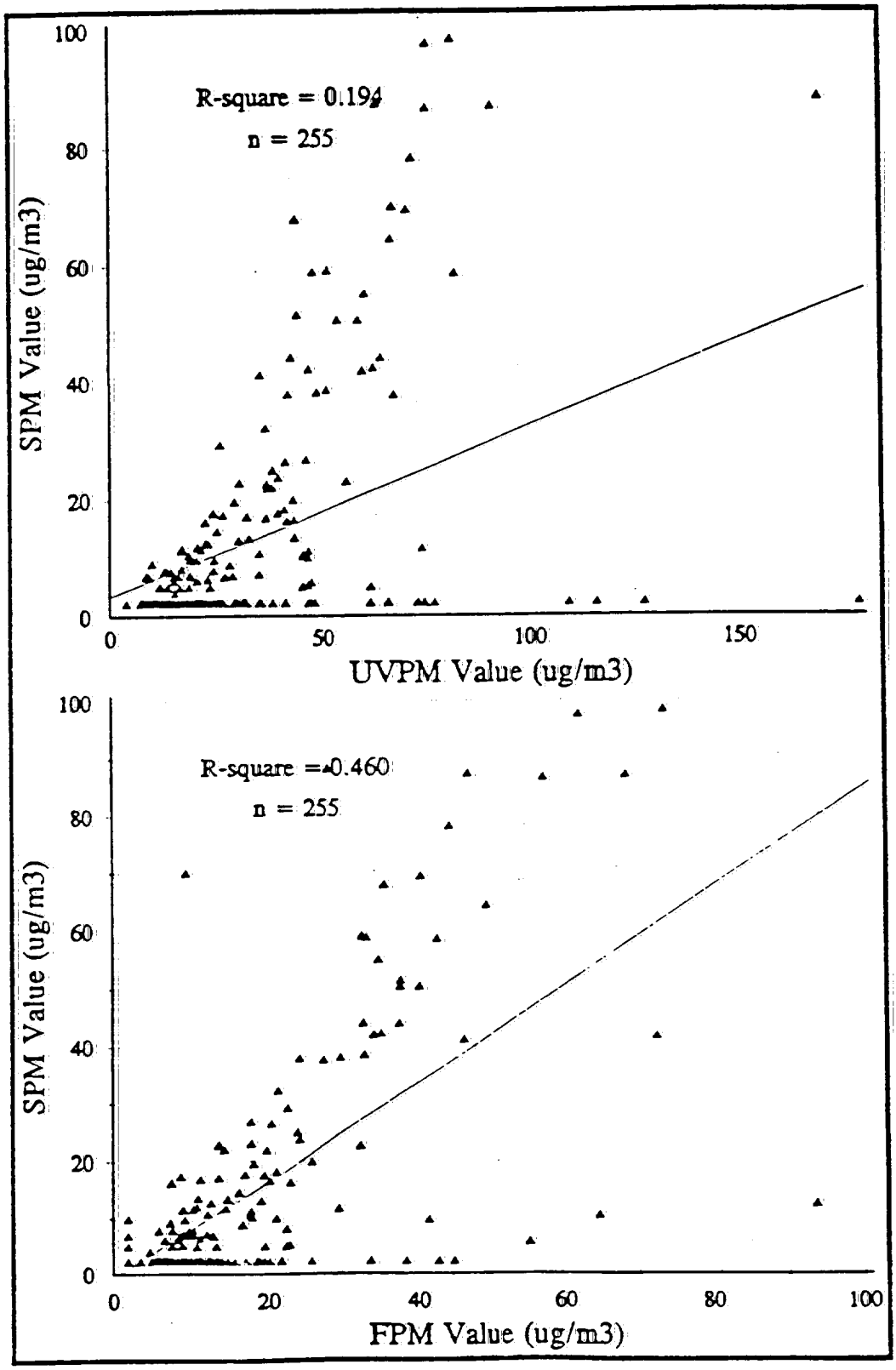
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 27B

CORRELATION OF SPM RESULTS WITH UVPM and FPM



Linear plot

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Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 28

CORRELATION STATISTICS COMPARING COTININE LEVELS WITH OTHER ANALYTES

Comparison	Number of subjects	Correlation	R-square	Figure number
SPM with pre-cotinine	254	0.25	0.06	24A + B
SPM with post-cotinine	248	0.38	0.14	24A + B
Nicotine with pre-cotinine	248	0.26	0.07	25A + B
Nicotine with post-cotinine	242	0.36	0.13	25A + B
SPM with nicotine	249	0.81	0.66	26A + B
SPM with PAS	255	0.21	0.04	26A + B
SPM with UVPM	255	0.44	0.19	27A + B

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4.12 Other observations and findings

The following items were not main objectives in this study but are of specific interest.

4.12.1 Leeds and Harrogate

Leeds is a large industrial city in comparison to the rural surroundings and non-industrial area encompassing the North Yorkshire spa town of Harrogate.

A. Subjective assessment

Figure 29 shows the subjective assessments of general air quality made by the subjects living and working in Leeds compared with those subjects living and working in Harrogate. The results show that for Leeds just over 5% thought the air quality was very good compared to almost 25% in Harrogate. Similarly just over 40% in Leeds thought the air quality was good compared to almost 60% in Harrogate. Significantly more than 10% in Leeds thought their air quality was poor with 1 to 2% claiming it was very poor. For Harrogate no one claimed very poor air quality with 1 to 2% claiming a rating of poor.

B. Direct measurement

Figure 30 shows the range mean and median levels of PAS and SPM found for subjects living and working in Leeds (Number 127) and those living and working in Harrogate (115). The remaining 13 subjects did not live and work in the same area.

The mean and median values for PAS indicate a noticeable significant bias towards Leeds in terms of higher PAS levels. Interestingly the SPM levels and SPM as a percentage of PAS are all higher for Leeds than Harrogate.

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Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

4.12.2 Primary sources of exposure to ETS by subjective assessment

Each subject was asked to assess their own principal sources of exposure to ETS in the six months prior to the start of the study (Question 20). They were asked to provide their four main choices and rank them in order of significance. Leisure work and travel were included in the list of choices, but the 'home' was not an option so that exposure from members of the family including spouse or partner could be assessed. Figure 31 shows the distribution of these assessments. The fourth choice is excluded from the graphs because the majority of subjects failed to provide a fourth choice.

A. Primary source

More than 40% of subjects chose leisure followed by work (27%) spouse or partner (10%) or friends (6%) as their primary sources. Less than 1% claimed no exposure or 'none'. Other members of the family (excluding spouse or partner) amounted to less than 7%. Own smoking was chosen by less than 1% with travel at about 3% (see Figure 31B). So the ranking for primary sources of exposure to ETS was assessed to be:

LEISURE > WORK > SPOUSE OR PARTNER > OTHER MEMBERS OF THE FAMILY > FRIENDS

B. Secondary source

Leisure was again chosen by more than 25% of subjects as their second source of overall exposure. The distribution pattern is for second sources, however, more spread out. Work, other people and friends were all between 11 and 13%. The ranking was assessed to be:

LEISURE > OTHER MEMBERS OF THE FAMILY > FRIENDS > WORK

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Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

C. Third source

In this case, more than 50% of subjects replied 'none' or provided no answer for their third choice, followed by other people (~ 13%) with friends, leisure and work all between 5 and 9%. Spouse or partner was chosen by less than 2% with the remaining members of the family rated as ~ 8%.

Direct measurements for all these categories was not attempted in this study. Subjectively the study indicated that most people believe their primary exposure occurs firstly at leisure then at work. One in ten claim their primary source is from their spouse or partner. Similarly most subjects did not rate their exposure from other members of the family as significant contributions to their total ETS exposure. Travel was not considered as a major source of exposure.

Figure 32 shows the assessments made by all subjects (48) who claimed their spouse or partner were smokers. From these graphs nearly 50% claim their primary source of exposure was not their spouse or partner.

Figure 33 shows the assessments made by all subjects (133) who claimed their spouse or partner were non-smokers. These distribution graphs show leisure followed by work as their primary source of ETS exposure. These graphs are near identical to the overall assessment of Principal Source of ETS exposure Figure 31.

4.12.3 Pre and post cotinine levels

When pre and post cotinine values for this study are plotted against each other (See Figure 34) R-square = 0.31 suggesting limited correlation. This could be due to differences in the previous 24 hours from the monitoring period relating to time of exposure. Part of the explanation could also be the inadequate limit of quantification of the method of analysis at the low levels found on this study.

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Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

4.12.4 3-Ethenylpyridine

It was not an objective of this study to compare the levels of 3-ethenylpyridine with those of other direct measurements. However, it was possible to analyse for 3-ethenylpyridine during the nicotine assay.

Figures 35A and B show a plot of 3-ethenylpyridine against SPM and nicotine using logarithmic and linear scales respectively with best fit straight lines for each case. The R-square values for SPM = 0.61 and nicotine = 0.72.

This correlation with nicotine can be regarded as reasonably good and the 'best' correlation of all the measurements compared on this study.

There are a significant number of cases where values were obtained for nicotine where corresponding 3-ethenylpyridine values are below the limit of determination.

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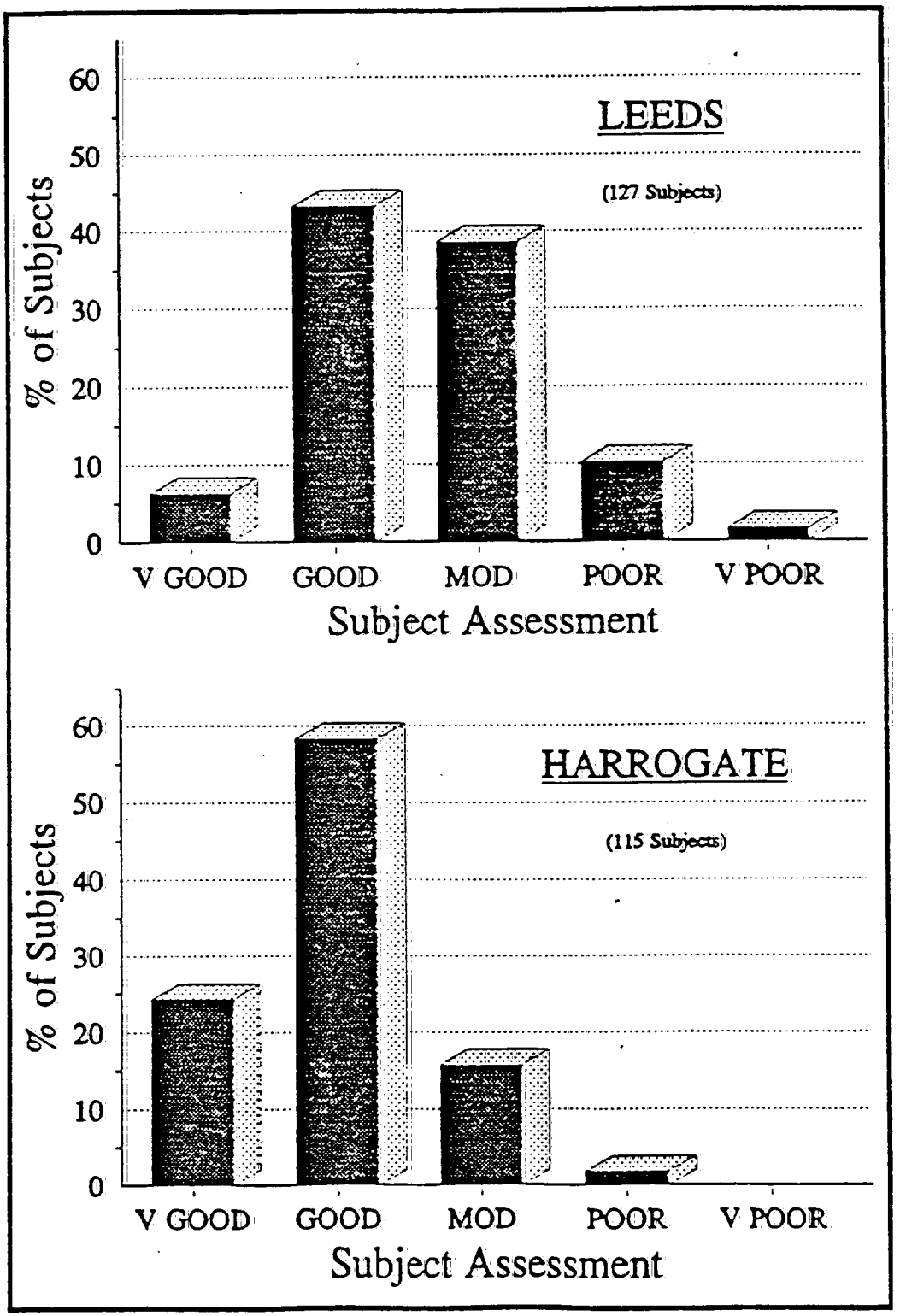
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 29

SUBJECTIVE ASSESSMENT OF GENERAL AIR QUALITY

LEEDS vs HARROGATE



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Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 30

SUMMARY OF THE RANGE OF PAS AND SPM LEVELS FOR HARROGATE AND LEEDS

		Harrogate	Leeds
	Number	115	127
PAS ($\mu g/m^3$)	Minimum	20	29
	Maximum	995	1219
	Mean	157	203
	Median	123	164
SPM ($\mu g/m^3$)	Minimum	2	2
	Maximum	98	159
	Mean	8	17
	Median	2	2
% SPM of PAS	Minimum	0.2	0.4
	Maximum	49.2	60.0
	Mean	5.5	8.5
	Median	2.6	2.5

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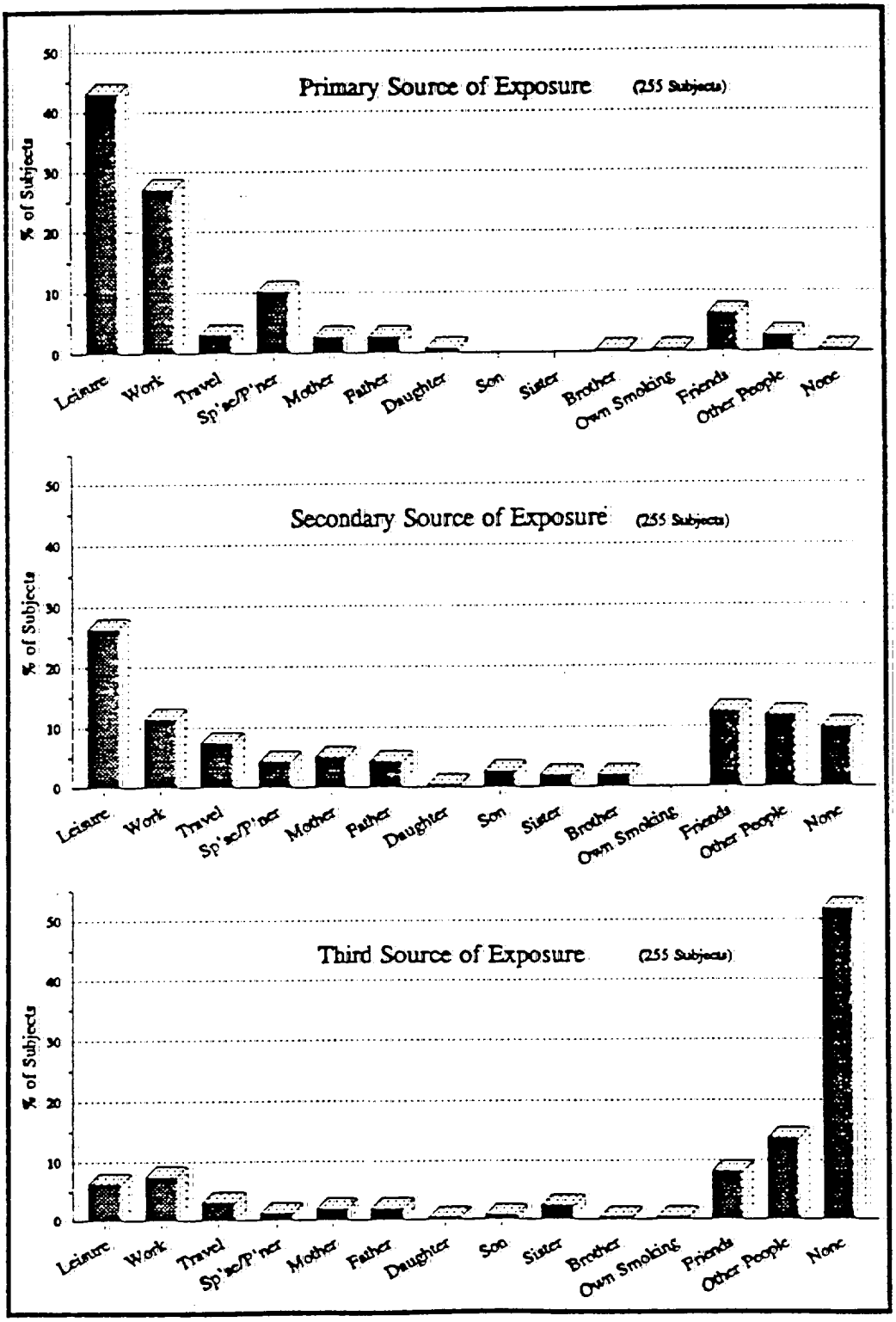
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 31A

SUBJECTIVE ASSESSMENT OF PRINCIPAL SOURCES OF OVERALL ETS EXPOSURE



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Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 31B

SUBJECTIVE ASSESSMENT OF PRINCIPAL SOURCES OF OVERALL EXPOSURE

Description	Number (%) subjects					
	Primary		Secondary		Third	
Work	69	(27.1)	29	(11.4)	19	(7.5)
Travel	8	(3.1)	19	(7.5)	8	(3.1)
Leisure	110	(43.1)	67	(26.3)	16	(6.3)
Spouse/partner	26	(10.2)	11	(4.3)	5	(2.0)
Father	7	(2.7)	11	(4.3)	5	(2.0)
Mother	7	(2.7)	13	(5.1)	5	(2.0)
Son	-	-	7	(2.7)	2	(0.8)
Daughter	2	(0.8)	1	(0.4)	1	(0.4)
Brother	1	(0.4)	5	(2.0)	1	(0.4)
Sister	-	-	5	(2.0)	6	(2.4)
Friends	16	(6.3)	32	(12.5)	21	(8.2)
Other people	7	(2.7)	30	(11.8)	35	(13.7)
Own smoking	1	(0.4)	-	-	1	(0.4)
None	1	(0.4)	4	(1.6)	18	(7.1)
No data	-	-	21	(8.2)	114	(44.7)
TOTALS	255		255		255	

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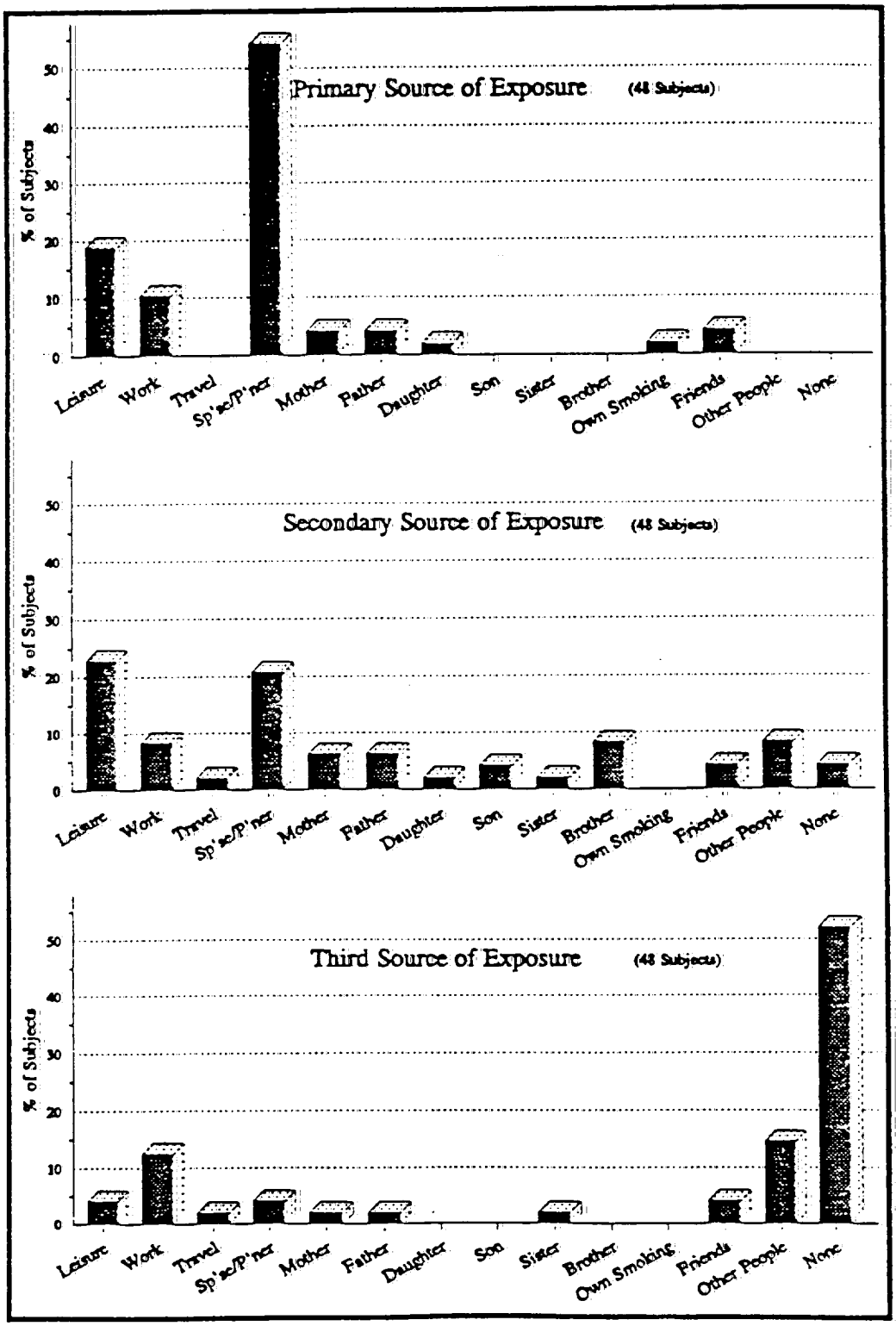
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 32

ASSESSMENT OF PRINCIPAL SOURCES OF OVERALL ETS EXPOSURE (SUBJECTS MARRIED TO SMOKERS)



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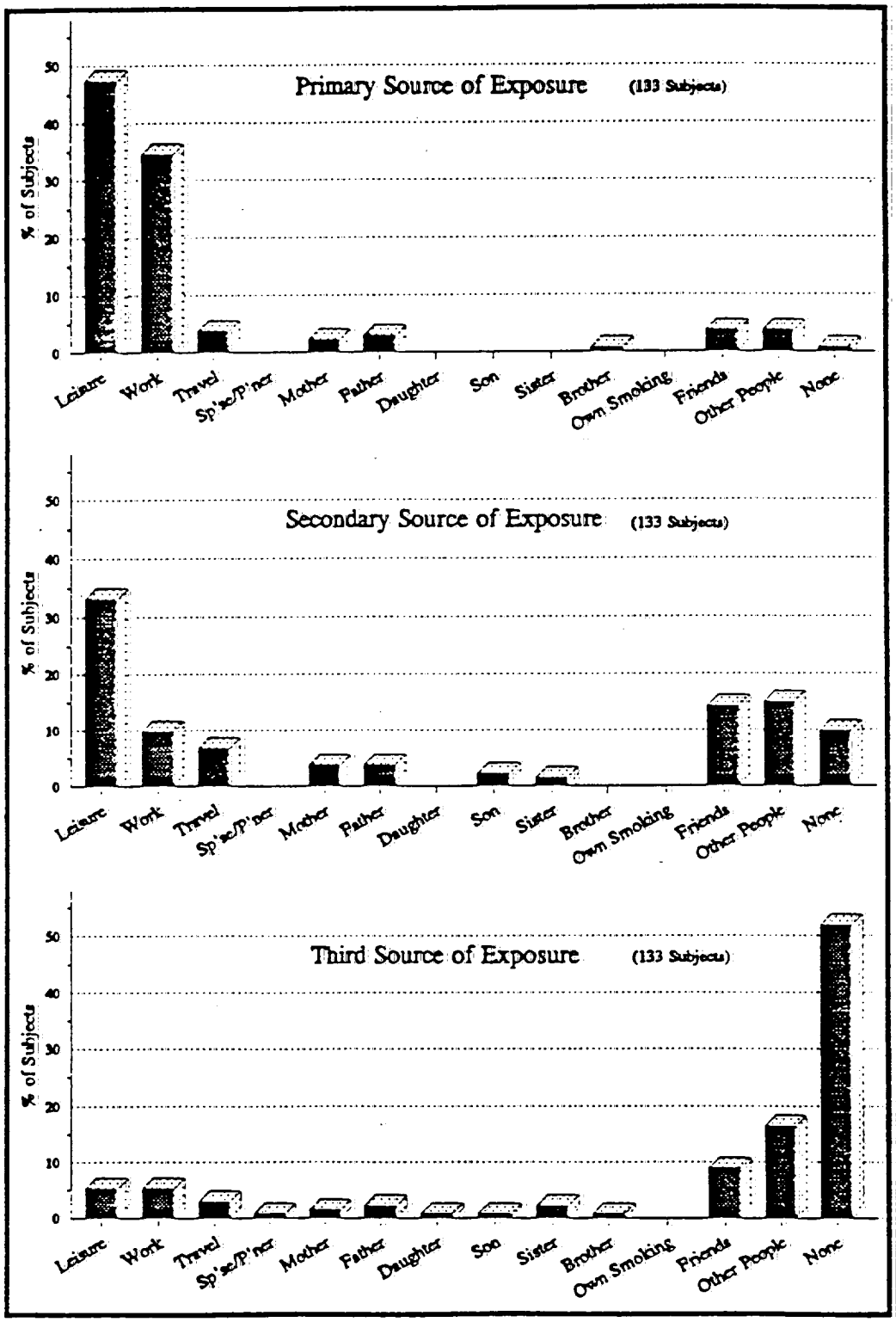
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 33

ASSESSMENT OF PRINCIPAL SOURCES OF OVERALL ETS EXPOSURE (SUBJECTS MARRIED TO NON-SMOKERS)



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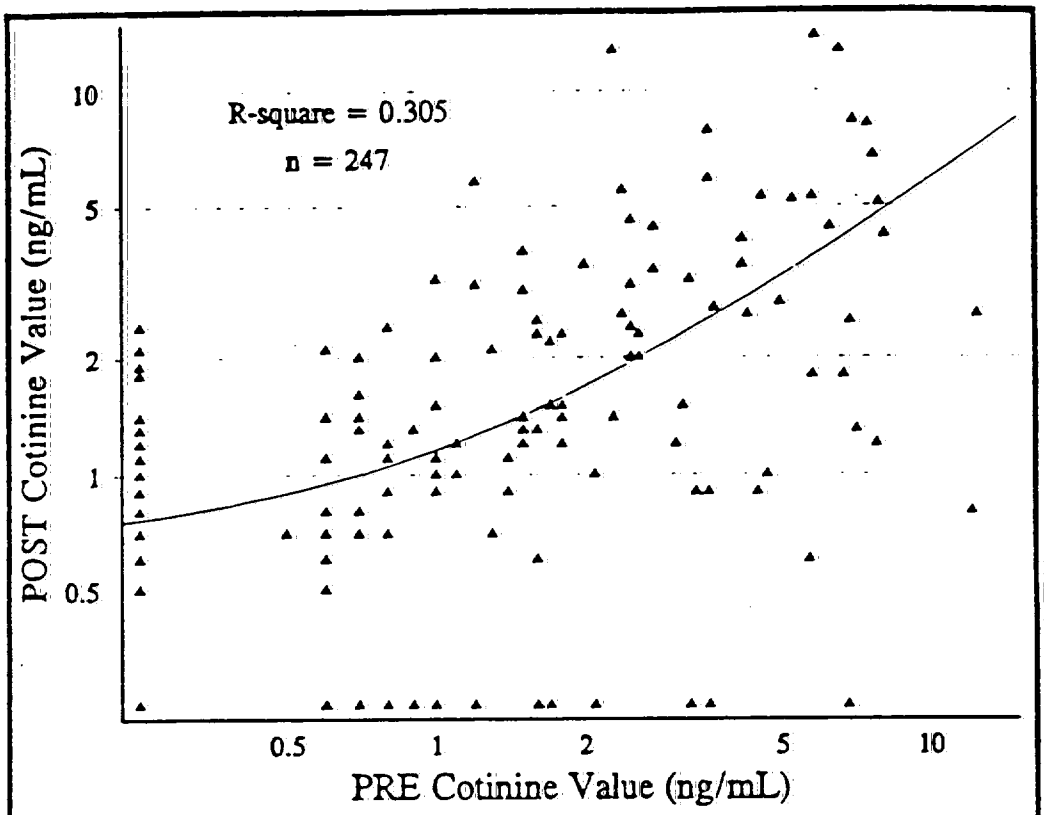
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

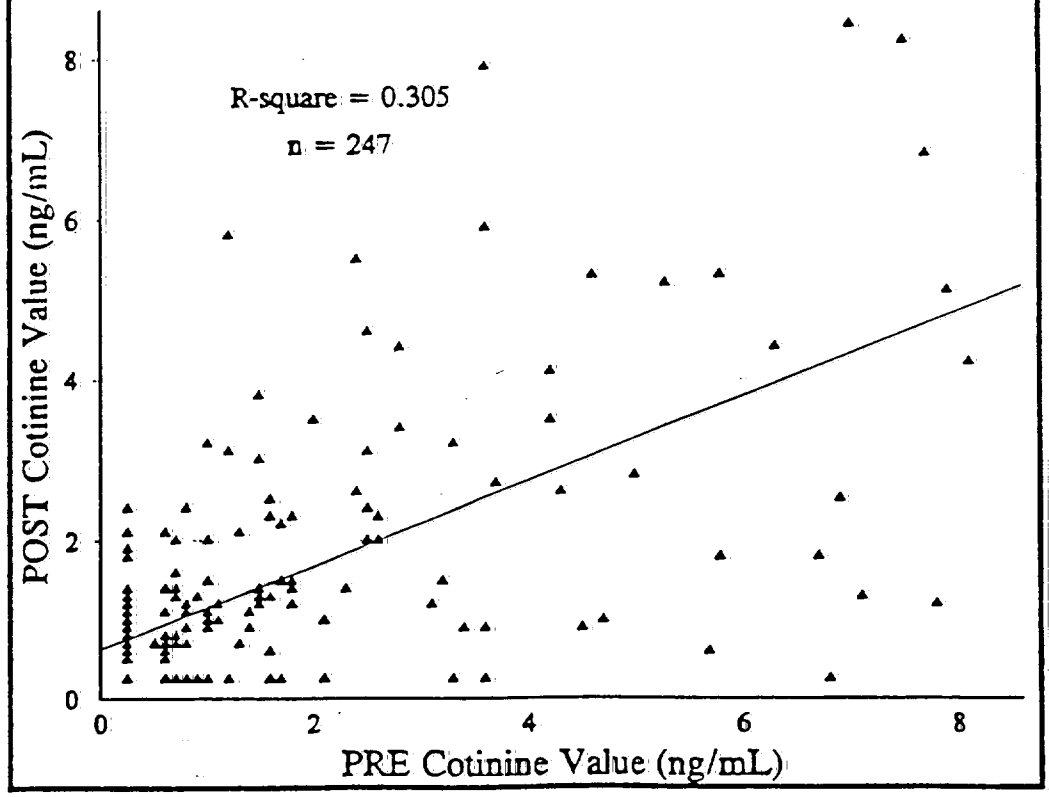
FIGURE 34

CORRELATION OF "PRE" AND "POST" COTININE RESULTS

Logarithmic plot



Linear plot



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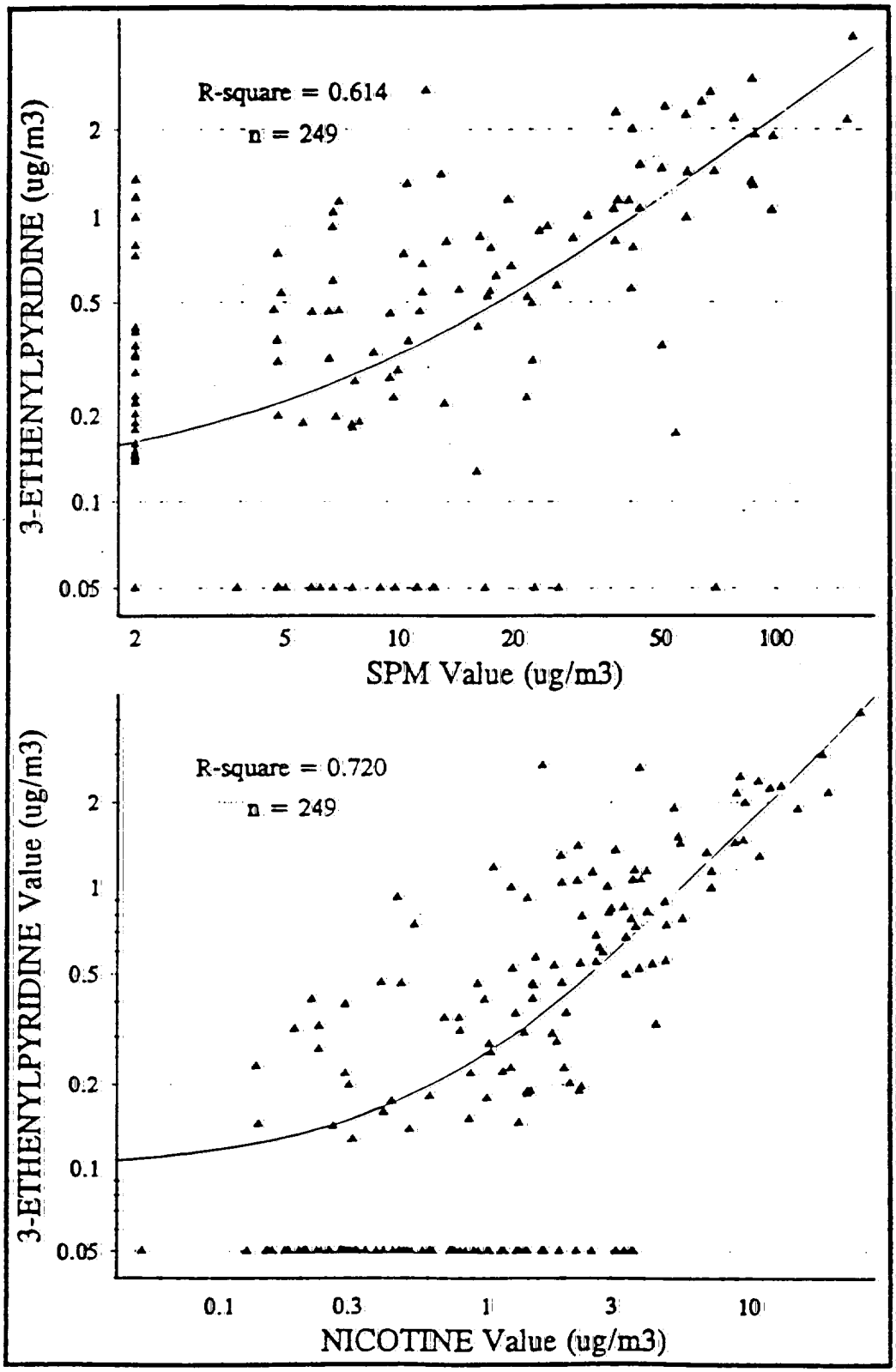
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 35A

CORRELATION OF 3-ETH RESULTS WITH SPM and NICOTINE



Logarithmic plot

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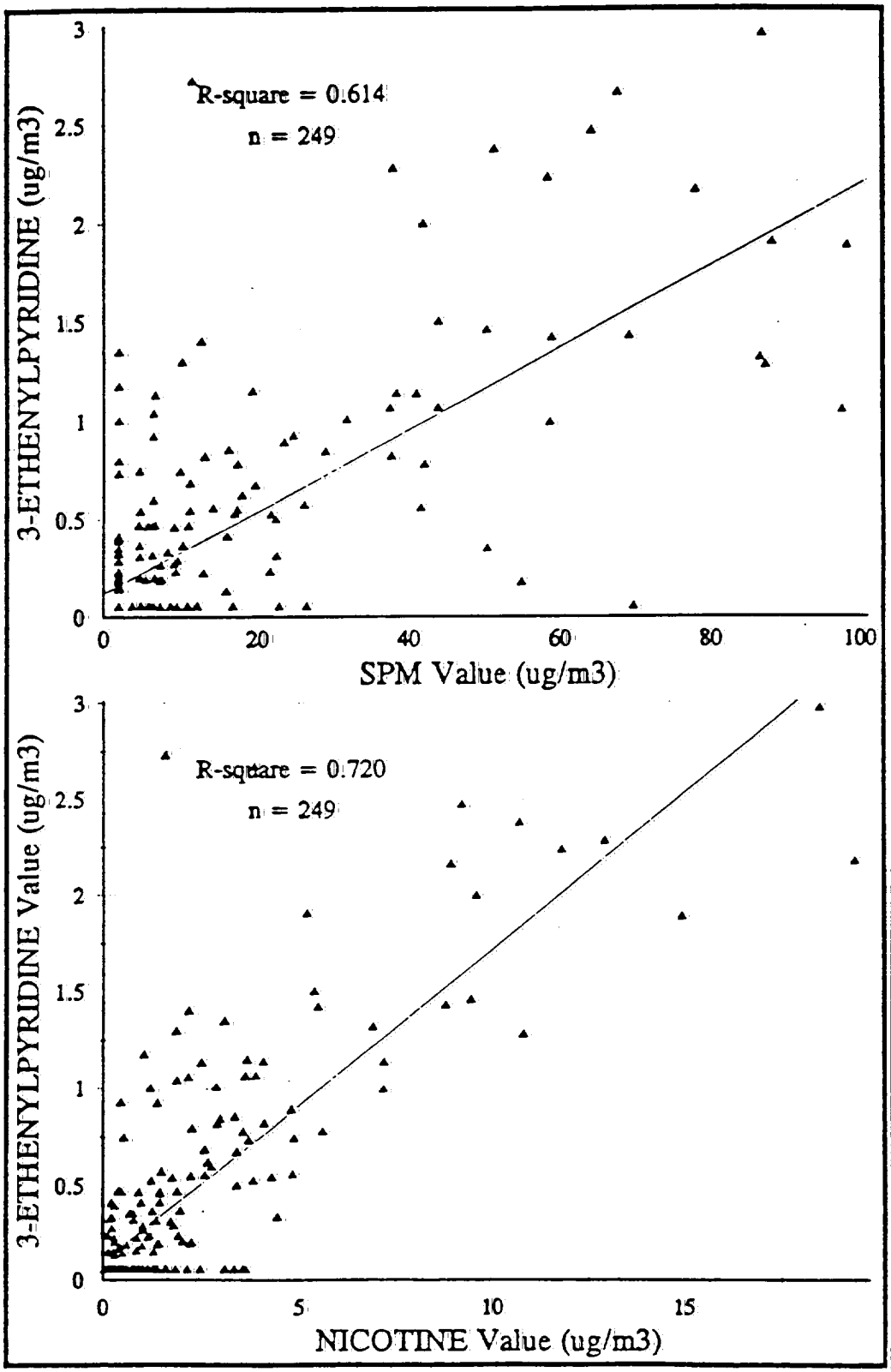
Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

FIGURE 35B

CORRELATION OF 3-ETH RESULTS WITH SPM and NICOTINE



Linear plot

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Source: https://www.industrydocuments.ucsf.edu/docs/nkvj0000

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